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ABSTRACT

Reported are the results of a review of the National Institutes of Health's (NIH) system of peer review. Recommendations presented include: (1) that a formalized NIH Grants Peer Review Appeals System be established; (2) that NIH periodically announce all upcoming vacancies on review groups; and (3) that review of grant applications should continue to be closed to the public. (SL)

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VOLUME I

GRANTS PEER REVIEW

REPORT TO THE DIRECTOR, NIH
PHASE I

DECEMBER 1976

NIH GRANTS PEER REVIEW STUDY TEAM

SE 022 889

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : Director, NIH

DATE: December 29, 1976

FROM : NIH Grants Peer Review Study Team

SUBJECT : Submission of Study Team Report

The NIH Grants Peer Review Study Team is pleased to submit to you the attached report. This report, Phase I, is based on a careful study of the issues by the Study Team and others at NIH and, in part, on the testimony presented at three public hearings, the letters received from the scientific community and the general public, and the results of a survey of NIH review group members. Phase II, to be completed in late 1977, will present a detailed analysis and evaluation of the letter responses and testimony from the public hearings; and will include the completed analysis and evaluation of the survey of IRGs and Council members.

The Study Team's report and recommendations are presented in Volume I. Volume II presents background appendices and Volume III is a collection of supplementary reports.

We have prepared a series of recommendations which we believe are central to the goal of not only maintaining but also improving the quality of the peer review system and thus of the biomedical research supported by NIH. We wish to call particular attention to several recommendations which represent a marked departure from the current peer review procedures or are deserving of special consideration:

- That a formalized NIH Grants Peer Review Appeals System be established, central to which is the establishment of a position of OMBUDSMAN to be appointed by the Director, NIH.
- That NIH should periodically announce all upcoming vacancies on initial review groups and invite suggestions regarding candidates for specific groups.
- That authority to establish or discontinue Initial Review Groups should be delegated to the Director, NIH.
- That NIH should seek to have the authority for selection and appointment of members of Advisory Councils/Boards delegated to the Assistant Secretary for Health, HEW.

- That those portions of the meetings of advisory groups which involve the review of grant applications should continue to be closed to the public (including those submitting applications), either under current exemptions to the open meeting requirement or through legislation.

- That, as soon as practical after a National Advisory Council or Board completes the review of a grant application, the Bureau, Institute, or Division should routinely send the associated summary statement with the priority score displayed to the principal investigator named in the application.

- That the Director, NIH, should take immediate steps to limit the workload of all Initial Grant Review Groups to a level compatible with maintaining the high quality of review.

The Study Team also addressed and developed recommendations concerning a variety of other key issues. These include identification and special consideration of unorthodox research approaches, the need for a single priority score convention for use throughout NIH in lieu of the present dual score system, conflict of interest procedures applicable to review group members, membership of employees of profit-making organizations in initial review groups, extension of peer review procedures to cover the assessment of business management practices in large grant applications, and opportunities for improving the grants peer review system through a continuing program of prospective studies involving specific procedures. Furthermore, the Study Team believes that all of the issues it considered are important and that, taken together, its recommendations form a self-consistent ensemble of actions which will do much to insure that the NIH grants peer review system remains a model of scientific and administrative excellence.

We believe that the report of the Study Team, and particularly its recommendations, will be of considerable interest to the biomedical community, the general public, and the NIH extramural staff. We have copies available for distribution if you wish to share the report with your staff or advisors.

Members of the Study Team are ready to assist you and your staff in the implementation of the recommendations presented in this report if you so wish.

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PREFACE

The NIH Grants Peer Review Study Team is pleased to present this report to the Director, NIH, for his consideration. The April 28, 1975, statement of the Acting Director, NIH, established and set forth the charge to the Study Team. In one of a series of assigned responsibilities, the Study Team was asked to "Examine in critical detail the entire process of peer review and make, where necessary, recommendations for modifications or change...." It is hoped that the present study will be one of a number of other studies of the NIH peer review system, and that other study groups will address aspects of the peer review process not covered in this report.

Acknowledgements:

As Chairperson, I would like to acknowledge the efforts of all members of the Study Team and the Study Team subcommittees who took time from already busy work schedules to participate in this series of studies and deliberations. Listed hereafter are the Study Team members and the membership of the subcommittees.

Other individuals contributed to the work of the Study Team in special and important ways. Particular thanks go to Dr. Mathilde Solowey, who served as Executive Secretary to the Study Team. She played a crucial role in facilitating and coordinating the work of the Team, and joined as a full participant in our deliberations and the preparation of the report.

Ms. Pearl Cooper Williams, as consultant to the Survey Subcommittee, prepared the final survey questionnaire, supervised the distribution and collection of the survey questionnaires, and designed and conducted the analysis of the survey data and prepared lucid narrative comments, with the general guidance and support of the subcommittee. She has also prepared special analytic reports to relate the findings of the survey to important issues addressed by the Study Team. She was essential to the successful completion of the survey, and we are much in her debt.

Dr. Catherine Henley prepared the detailed description of the NIH peer review system as one of her first assignments at NIH, and participated in other Study Team efforts. We are most indebted to her for her contributions.

Mr. Sidney Gottlieb, Division of Management Policy, Office of Administration, made arrangements for the public hearings and the printing of this report and served as a staff resource. Particular acknowledgement is due for his excellent efforts.

Ms. Sue Fremeau, Committee Management Officer, NIH, was most helpful and served as an important resource.

Ms. Virginia Ono, secretary to the Chairperson, served as secretary to the Study Team with great distinction.

Particular thanks are extended to Ms. Alice Shoemaker for the major typing of the report. Others who have been of so much help in typing are Ms. Joan Clements, Ms. Sandra Shade, and Ms. Emily Johnson.

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NIH should conduct studies of:

(1) Variations in individual reviewer and review group behavior in rating applications, over time, and among different IRGs, and of the factors which act to increase or decrease such variability;

(2) Variations in the quality of grant applications assigned to a given IRG from one review round to the next, over time; and variations in the quality of grant applications assigned to the IRGs;

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INTRODUCTION

INTRODUCTION

The past 20 years have seen a demonstrable growth of the extramural grants program supported by the National Institutes of Health (NIH). Specifically, support for NIH research grant awards grew from $32 million in FY 1955, to $473 million in FY 1965, to $1.12 billion in FY 1975. In 1975, 11,243 competing research grant applications were reviewed by peer review groups. Additionally, several thousand other kinds of applications were received, such as individual and institutional National Research Service Award applications, resource applications, and research career program awards. In 1975, the traditional investigator-initiated research grant applications requested a total of $887 million (for the first year only of multi-year applications). As a result of peer review evaluations, $431 million were recommended for approval and $318 million in first-year direct-cost funds were awarded for competing projects.

The level of interest in the NIH extramural research program and its operation is exceedingly high in the biomedical scientific community, which is increasingly dependent for research support on the availability of federal funds. Equally high interest is shown by the general public, which looks to this use of federal funds, for support of biomedical research, as a means of ultimately improving the health care of the nation.

The extramural research program is essential to the mission of NIH and it is therefore equally essential that it be of the highest quality. Since the inception of the extramural program at NIH, the gauge for selection of research and other grant activities for support has been by means of peer reveiw. Traditionally, NIH routinely monitors and administers the peer review system to assure its continued quality and effectiveness and to provide a continuous process of improvement.

Early in 1974, a two-day seminar was held by NIH officials to examine and appraise the extramural research and training grant review system, and the use of peer review and public advisory groups by NIH for its rapidly growing extramural research grants program.

A series of recommendations emerged from the seminar, including one specifically directed toward the need for an NIH Study Team to continue the study of the peer review system. Responding to the recommendation, in the spring of 1975, the Acting Director of NIH established the NIH Grants Peer Review Study Team (GPRST) consisting primarily of NIH personnel and including a member of the Office of General Counsel (OGC), DHEW, assigned to NIH. The Acting Director designated for membership on the Study Team, individuals whose expertise he considered desirable and necessary to accomplish the objectives.

Summary of the Charge to the Study Team

The Study Team was asked to:

> ". . . conduct a detailed and comprehensive study of the NIH peer review system. This study, in broad outline, should focus on the philosophy and procedures of peer review, its applicability to the

> NIH awarding instruments and programs, the attributes and problems of alternatives, and the role and character of peer review in the decision-making process at NIH."

More specifically, the Study Team was asked to:

> "Examine in critical detail, the entire process of peer review and make, where necessary, recommendations for modifications or change. In addition to other items which the Study Team may wish to consider, specific attention should be given to: (1) selection procedures and criteria for advisory committee members; (2) the need and feasibility for an NIH policy defining the administrative and scientific relationships of the staffs responsible for the technical merit review of grant applications conducted in awarding Institutes and Divisions and those responsible for scientific program management; (3) the need, advantages, and disadvantages for a technical merit review "appeal" mechanism for applicants and an assessment of the process currently in use; (4) the role and character of peer review in the decision-making process at NIH; (5) the capability of the peer review system to accommodate a really new or unusual scientific idea, . . . (6)assess the impact and make recommendations relative to peer review and provisions of the Freedom of Information Act (FOIA), the Federal Advisory Committee Act (FACA), and the Privacy Act (PA)." (Attachment 1 - Charge to the Study Team.)

The Study Team was instructed to examine the positive features of the peer review system as well as to assess critically any deficiencies that might be suggested: Overall, in examining the positive features, the Study Team feels that peer review exercises the single most powerful influence on the continued high quality of the Nation's biomedical research effort and encompasses several fundamental characteristics. These include the selection of participants who are judged according to their expertise and a system of checks and balances designed to protect the process from considerations extraneous to the criterion of high scientific quality.

Furthermore, the Study Team believes that confidence in the system is justified and has evolved primarily from the steadfast position maintained by NIH that it is, first and foremost, the high scientific quality of the supported research, as defined by the peer review system, which should govern the content of the national biomedical research effort. Allegiance to this principle by a succession of program managers at NIH, over a period of many years, has resulted in a research program not seriously challenged in regard to its fundamental, scientific quality.

The Study Team further believes that the NIH research programs constitute a critical national resource, and that the quality of this resource has been successfully defined in the public interest by the unique administrative device of the peer review system. It is confident that the system will continue to provide such service with careful management and maintenance and an unswerving commitment to the application of the principles of scientific excellence.

ORGANIZATION OF THE STUDY

The Team recognized that, although as a group consisting primarily of NIH officials, it could bring a significant collective perception of the peer review system as seen from the viewpoint of those who know the system best and who are also responsible for its operation, nevertheless, its appraisal of the peer review system would be strengthened by input from the external community. Accordingly, the Study Team sought opinions about the peer review system and suggestions for its improvement from the broadest possible range of biomedical researchers and interested lay individuals other than scientists.

To accomplish the tasks necessary to fulfill its mission, the Study Team was organized into a series of subcommittees. Each subcommittee was chaired by a member of the parent Study Team, but the membership generally included both Study Team members and other NIH staff as well. Participation of the latter served to expand the representation and provided added expertise. Progress and completed subcommittee reports were reviewed and modified as a result of discussion by the parent Study Team as a whole in order to assure concurrence and acceptance by all.

Certain specific issues were assigned to single Study Team members or small work groups in order to develop position papers. These served as a basis for discussion and for incorporation into the body of the report and as recommendations of the whole Study Team. These discussions generally resulted in one or more revisions prior to concurrence and/or acceptance of the document.

A brief statement regarding each of the subcommittees follows: A more detailed description of the subcommittees' activities and considerations will emerge from the body of the report.

- Subcommittee on Studies of Peer Review Systems

  The Subcommittee examined previous studies of the NIH Peer Review System and also reviewed briefly peer review systems in use in other federal agencies and other countries.

- Hearings Subcommittee

  The Subcommittee prepared for and planned three public hearings in different parts of the country to obtain the perceptions and/or suggestions of the external community in regard to NIH peer review. The Subcommittee also assessed, analyzed, and evaluated the information derived from the hearings.

- Survey Subcommittee

  The Subcommittee developed a survey questionnaire which was used to obtain opinions regarding the NIH peer review system from members of all current Initial Review Groups (IRGs) and Advisory Councils attending the November 1975-February 1976 meetings, and subsequently assessed, analyzed, and evaluated the findings.

- Subcommittee on Appeals

  The Subcommittee evaluated the desirability of establishing a grants peer review appeals mechanism, and, having determined the need for such a system, proceeded to develop appeals procedures.

- Subcommittee to Review Legal Aspects of Peer Review

  The Subcommittee examined the legal considerations related to peer review, such as Freedom of Information legislation, the Privacy Act, confidentiality, conflict of interest, chartering of committees, ad hoc reviewers, and selection of committee members, as well as the impact of these factors on the peer review system.

- Subcommittee on Business Management Practices

  The Subcommittee studied the impact of business management practices on peer review, and review procedures related thereto. It also reviewed and made recommendations concerning the establishment of policies regarding the role of a business consultant in peer review.

Additional topics considered by the Study Team and dealt with in depth in the body of the report or its appendices were the following:

1. Current procedures for selection of Initial Review Group, Special Initial Review Group, and Advisory Council members and modifications of these procedures.
2. The effect of review workload on quality of peer review, and suggestions to lessen the workload.
3. Summary statements and priority scores.
4. Premature disclosure of the outcome of peer review.
5. The role of peer review in support of innovative research.
6. The role of peer review in NIH decision-making.
7. The separation of peer review from program responsibilities.
8. The need for improved communication between NIH and the external community as well as within internal NIH components.
9. An analysis and evaluation of letter responses from the external community commenting on aspects of the NIH peer review system.

The Study Team also prepared a comprehensive description of the NIH grant application peer review process. (Appendix C).

ATTACHMENT 1

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : B/I/D Directors
ECEA Members
OD Staff

DATE: April 28, 1975

FROM : Acting Director, NIH

SUBJECT: Establishment of NIH Grants Peer Review Study Team

During the spring of 1974, the Executive Committee for Extramural Affairs sponsored and participated in a seminar on peer review. The purpose of this seminar was to identify and evaluate the objectives of the peer review concept, document strengths and weaknesses of the NIH peer review system, and discuss possible modifications or alternatives. This effort derived from the dual perception that NIH staff, who know the system best, should be in a unique position for its appraisal and that the system should indeed be subjected to periodic in-depth evaluation to assure its continued quality and effectiveness.

In addition to reviewing previous studies of peer review and the resulting suggestions and related criticisms, the ECEA Seminar format provided for a current appraisal of the Extramural Research and Training Grant Review System and a re-examination of basic concepts and procedures. This included a consideration of prepared papers followed by panel discussions and the ratification of a set of recommendations which were part of a final report of the seminar submitted to me in December, 1974.

Following up a major recommendation in the final report from the Planning Committee for the ECEA Seminar on peer review, I am establishing an NIH study team to extend the efforts of ECEA and conduct a detailed and comprehensive study of the NIH peer review system. This study, in broad outline, should focus on the philosophy and procedures of peer review, its applicability to the NIH awarding instruments and programs, the attributes and problems of alternatives, and the role and character of peer review in the decision-making process at NIH. In addition to this major charge, I am asking that the study team:

- Review previous and on-going studies and analyses of the NIH and other systems of peer review, evaluate recommendations and, in the course of the work of the study team, initiate additional analyses or activities as necessary for accomplishments of team objectives.

- Articulate in detail the philosophy, objectives, procedures, and accomplishments of peer review. From such descriptions, the study team should prepare or have prepared one or a series of papers for dissemination to the public and the scientific community as a means of achieving a general understanding and appreciation of a system which has evolved to its present state over a period covering a quarter of a century.

- Examine in critical detail the entire process of peer review and make, where necessary, recommendations for modifications or change. In addition to other items which the study team may wish to consider, specific attention should be given to (1) selection procedures and criteria for advisory committee members, (2) the need and feasibility for an NIH policy defining the administrative and scientific relationships of the staffs responsible for the technical merit review of grant applications conducted in awarding Institutes and Divisions and those responsible for scientific program management, (3) the need, advantages, and disadvantages for a technical merit review "appeal" mechanism for applicants and an assessment of the process currently in use, (4) the role and character of peer review in the decision-making process at NIH, and (5) the capability of the peer review system to accommodate a really new or unusual scientific idea.

- Evaluate the need for enlarging or altering the type of NIH staff training and communications to improve and maintain coordination and interaction between separate NIH peer review activities.

- Assess the impact on and make recommendations relative to peer review and provisions of the Freedom of Information Act, the Federal Advisory Committee Act, and the Privacy Act.

To accomplish the above objectives and to consider other questions and recommendations concerning the peer review system for grants, the following study team is appointed by this memorandum:

Dr. Ruth Kirschstein	Director, NIGMS, Chairperson
Dr. Robert Akers	Policy and Procedures Officer, OERT, OD
Dr. George Brooks	Assoc. Director, Extramural Program Activities
Mr. Carl Fretts	Director, Division of Contracts and Grants, OA, OD
Dr. Norman D. Gary	Executive Secretary, SSS, DRG
Dr. William Goldwater	Assistant to the Associate Director, OCR, OD
Dr. Phillip Gorden	Acting Clinical Director, CI, NIAMDD
Dr. Jerome Green	Director for Division of Extramural Affairs, NHLI
Dr. Ann A. Kaufman	Research Grants Officer, OERT, OD
Dr. William Raub	Assoc. Director, Extramural & Collaborative Program, NEI
Dr. S. Stephen Schiaffino	Associate Director for Scientific Review, DRG
Dr. Katherine S. Wilson	Executive Secretary Genetics SS, DRG

In pursuing its work, the study team is requested to make full use of all necessary resources both within and external to the NIH. Within this framework, it is expected that appropriate consultation will be made with members of the scientific and grantee community and current and former members of NIH Advisory Groups in order to examine perspectives, criticisms, and suggestions for alternatives or improvements to the peer review system. The office of the Associate Director for Extramural Research and Training will make available to the study team the full report of the ECEA Seminar on peer review and other such documents and previous studies that will be useful in its deliberations.

I am asking that the study team report interim activities to me through the Associate Director for Extramural Research and Training and that a final report with recommendations be submitted no later than May 1, 1976.

I would greatly appreciate all cooperation and assistance that you and your staff can render the study team. In addition, if there are comments or suggestions which you or your staff feel may be useful to the study team, please communicate them directly to Dr. Ruth Kirschstein.

RW Lamont-Havers
Ronald W. Lamont-Havers, M.D.

STUDIES OF PEER REVIEW SYSTEMS

STUDIES OF PEER REVIEW SYSTEMS

Apparently, peer review procedures for health research supported by the Federal Government were initiated in 1902. At that time the Fifty-seventh Congress established a Scientific Advisory Board of non-Governmental scientists to assist the Surgeon General in the administration of the Hygienic Laboratory. In later years (1930) the Laboratory was renamed the "National Institute of Health" and the Advisory Committee was reconstituted and renamed the "National Advisory Health Council."

When the National Cancer Institute was established in 1937, the Cancer Act also provided the legal basis for the National Advisory Cancer Council. The Council was to play a key role in recommending the award of grants. These authorities and procedures were extended to grants and fellowships in all health research areas in 1944, when the Public Health Service Act was passed.

In 1946 the Director of the NIH recognized the need to establish a more formal advisory mechanism for the assessment of technical and scientific merit; the Division of Research Grants (DRG) was established and study sections or initial review groups came into existence in 1947. Thus, at that early date, the basis for the current NIH dual review system was established.

Over the years, since the very inception of the dual peer review system, there have been multiple studies of the NIH advisory structure and the review and approval system. As NIH review procedures have matured and developed, and as the extramural programs have expanded, these studies and surveys have become more frequent and extensive. Some were instituted by the Executive Office of the President, some by Congressional mandate, and some by the Department of Health, Education, and Welfare (DHEW) or the staff of NIH. The members of the Grants Peer Review Study Team (GPRST) have cataloged and reviewed these previous studies. Some focused in particular on NIH while others were of a more general character dealing with overall Federal policies. Those studies that seem particularly relevant to the current undertaking are briefly reviewed here.

In 1947, the same year that the DRG was established, the President established a scientific research board to study and report on Science and Public Policy. Volume 5 of its report is entitled "The Nation's Medical Research."(1) Even at this early stage, the Board noted that the use of advice from outside experts on research proposals presented a difficult dilemma. While the selection of experts from the leading hospitals, medical schools, and research institutes insured the best possible advice, on the other hand, as the Board noted, the majority of proposals to be evaluated were submitted by staff members or graduates of these same institutions. It was concluded that the advisory groups were providing splendid service to the Government and devoting conscientious thought and considerable time to the review and evaluation of the proposed projects while resisting any tendency to create research monopolies. The Federal Government was advised to continue its sound policy of utilizing outside scientific advisers.

In the mid-1950s, the Secretary of DHEW commissioned a report on "The Advancement of Medical Research and Education Through the DHEW." This report, commonly known as the "Baynes-Jones Report," was issued in 1958. (2) The consultants recommended the expansion of medical research and education, and projected that total national medical research expenditures should increase from the 1957 level of $330 million to approximately $1 billion per year by 1970. The report briefly described the NIH peer review system and noted that the advisory structure and procedures were designed for a relatively small grants program characterized by grants of modest size. The report predicted that the NIH extramural program of research support would evolve towards larger grants for broadly defined purposes encompassing many disciplines and would require changes in the traditional study section system.

In 1960, the Senate Committee on Appropriations requested advice from a committee of consultants on Federal support of medical research. There is no indication (in this so-called "Bo Jones Report") that the appointed committee made an indepth study of review procedures. However, in determining that funds appropriated by the Congress for the support of research on major disease problems had been expended by Federal agencies with remarkable efficiency, the Committee report included the following statement:

> "The National Institutes of Health, which Congress has made its principal instrument for the disbursement of funds for medical research, has developed an extremely successful system for review and approval of applications for research grants, training grants, and fellowships. This plan, relying on close supervision of outstanding scientists, has assured consistently high standards for the research supported, gained the confidence of the scientific community, and maintained the traditional freedom of both institutions and investigators." (3)

Many similar statements were made in the November 1960 Report of the President's Science Advisory Committee (PSAC). "In its support of basic research, the government has usually relied on the advisory judgment of respected scientists, and in the main this advice has ensured that in those areas of research in which Federal support has been available, outstanding men have been able to attract substantial support. In this respect, the project method of research support has real values which should not be forgotten...." (4)

The Committee on Science and Public Policy of the National Academy of Sciences (under the Chairmanship of Dr. George B. Kistiakowsky) issued a report in 1964 concerning "Federal Support of Basic Research in Institutions of Higher Learning." (5) This report gives a history of the origin and the development of the Federal scientific establishment and discusses the use of grants and contracts, and peer review procedures, in a variety of Federal agencies. The study had its origin in a resolution passed by the American Society of Biological Chemists which requested an examination of Federal programs in support of fundamental research. The Committee expressed support for the panel system of peer review. However, disadvantages of the panel system of peer review were mentioned, including the workload accepted by scientists who participated, the increased time to complete the review of each proposal, and the potential difficulties when service on peer review groups is concentrated among too few individuals or institutions. The Committee also noted potential problems with interdisciplinary research, namely, that panels may not always reflect the current frontiers of research, or that the proposals may be sent to the wrong panels. Recommendations for the improvement of panel peer review were provided: (1) the use of more advisors and more frequent rotation; (2) the use of younger scientists on panels; (3) the inclusion of persons of breadth as well as specialization; the addition of members from allied fields; (4) the serious consideration of the advice of panels in order to maintain the conviction among advisors that their services are important; (5) the fact that overall budget review is appropriate to peer review, but detailed decisions on fiscal matters are not; (6) continuation of support of basic research by several agencies so that scientists will have access to more than one peer review process.

In that same year, 1964, the Select Committee on Government Research of the House of Representatives (the Elliott Committee) issued its report on national goals and policies. This Committee was established to provide the House of Representatives with an overall review of Federal research and development programs. Although none of the ten studies reported dealt primarily with NIH or with peer review, the Committee examined various methods used by Federal agencies to review applications for support. The Committee concluded that fellow scientists must rate both the competency of those presenting proposals and the ripeness of the field but that the evaluation criteria used must include value, economic, and political judgments, as well as broader judgments concerning scientific and technical matters. The Committee noted that the panel systems utilized by various agencies provided a training ground for the development of a pool of advisors required at higher policy levels. (6)

Perhaps the largest, most extensive, and most prestigious study of NIH was the one commissioned by President Kennedy and chaired by Dr. Dean Wooldridge. The Wooldridge Committee, supported by twelve working panels, submitted its report on "Biomedical Sciences and Its Administration" in 1965. (7) Detailed descriptions and analyses of the NIH peer review procedures are contained in various sections of that report, but particularly in the report of the Panel on Review Procedures. The first and most important general conclusion of the study was that the activities of NIH were essentially sound and that funds were being spent wisely and well in the public interest.

> "The opinion of the (Wooldridge) Committee, based on the extensive investigations of its consultants, is that the large majority of the intramural and extramural research supported by NIH is of high quality. We strongly approve the peer evaluation method of selecting recipients of extramural grants."

> "The Study Section Procedure utilizing scientific peer judgments is the best available method for awarding research grants." (7)

It is believed that the Wooldridge Committee conducted the most comprehensive and thorough review ever undertaken of a Federal science agency. Addressing itself specifically to the extramural programs, the Committee felt that despite increased loads on study sections, peer judgments should be preserved at all costs. Measures should be encouraged which would lessen the burden on study sections without usurping their function of scientific review. The Committee felt that extramural investigators would like more contact with and advice from scientists on study sections and would welcome more site visits, suggestions from study sections about improving research plans, and more explanations of why proposals were not approved.

In 1966, no fewer than three important reports were published. The Westrate Report, commissioned by the Bureau of the Budget, dealt with the management of Federally funded research programs in several areas, including biomedical sciences. Information was obtained by interview and questionnaire methods that involved Federal officials, university staff members, and officials at private foundations. The section of the report most relevant to review procedures is entitled "Improving the Quality of Federal Research Administration" and portions of this deal specifically with NIH methods, viz., "the most elaborate review procedures of any agency." (8)

The report recommends that:

> "Appropriate action should be taken to remove the statutory provision which prohibits the Surgeon General from authorizing approval of an NIH grant unless the grant has been expressly approved by the Advisory Council of the pertinent Institute.
>
> "With respect to proposal review procedures, the agencies should:
>
> a. continually evaluate the adequacy of the advice they obtain from proposal reviewers and the procedures they employ;
>
> b. provide sufficient administrative assistance and numbers of advisors to reduce the reviewers' workloads and insure that their time can be most profitably utilized;
>
> c. because of the advantages inherent in panels, use panels for scientific review to the maximum extent feasible; and
>
> d. when panels are used, rotate the membership and give consideation to geographic and university distribution in selecting appointees.

"In addition to their present procedures for dealing with possibilities of conflict of interest, agencies should:

a. stress the advisory nature of panel deliberations, and instruct the Government member present at such panel sessions to deal with potential conflicts which may arise.

b. bar a consultant or panel member from participating in general discussion about proposals submitted from any source in his own university, although he should be permitted to answer specific questions of fact regarding such proposals.

"As part of their review procedures, all agencies should request panel or consultant opinions regarding the general level of funding, major equipment requested, and fraction of investigator effort estimated for the project when such opinions appear to be relevant to deciding the merits of the proposal.

"Agencies should routinely distribute an award list to their proposal referees." (8)

The report of the Secretary's Advisory Committee on the Management of NIH Research Contracts and Grants (the Ruina Committee) was also published in March 1966.(9) Once again, the review procedures utilized in NIH extramural programs were examined and endorsed. The report of the Ruina Committee stated that:

"With the enormous expansion of the grant activity during the past decade, the Advisory Councils have found it necessary, as a practical matter, to rely almost entirely upon Study Sections, panels of distinguished scientists organized on the basis of scientific disciplines and medical specialties, to evaluate the scientific merits of grant applications. So large a volume of applications is now processed that Advisory Councils are almost entirely dependent upon summaries and "priority ratings" forwarded by the Study Sections.

"This inevitable dependence on 'peer groups' for preliminary screening and ordering of grant applications has not resulted in a mere 'rubber stamp' function for a Council. Rather, policy deliberations undertaken by a Council are often based upon questions concerning individual grants which are singled out by notations of the Study Sections, or by NIH staff or members of the Council at the time of meeting. Each Advisory Council member receives summaries of all of the applications for grants, and thus has a convenient reference file of current information to assist him in keeping up with the broad trends in research pertinent to his Institute's field of interest.

> "The effectiveness of these project grants in support of biomedical research is widely recognized, as is exemplified by the following comment of one of the panels of the Wooldridge Committee.
>
> "'The procedures followed in reviewing what are known as traditional research grants were instituted first and constitute the most thoroughly established, the most rigorously followed, the easiest to understand, probably the most widely admired of the activities included in the extramural programs of the National Institutes of Health.'"(8)

Later, in 1966, a special Congressonal subcommittee chaired by Congressman Paul G. Rogers investigated DHEW.(10) With respect to the function and adequacy of the NIH Advisory Councils, the Subcommittee endorsed the critique of the Ruina Committee. The Subcommittee noted that the NIH system of review and approval was considered desirable by the scientific community primarily because proposals were independently judged by peers and not by Government officials. The NIH grant review system thus separated the assessment of scientific merit from the staff responsibility for program administration. In the opinion of the Subcommittee, one of the weaknesses of the NIH system resulted from the fact that it was devised for a much smaller volume of grant applications; it was noted that it was virtually impossible for review groups, including the Councils, to conduct completely satisfactory review in the limited time available.

Among other things the Rogers Subcommittee stated that:

> The increase in the number of study sections had not kept pace with the increase in the number of applications; the explosion of scientific knowledge as a result of increased emphasis placed on research; the unrealistic assumption that the combined knowledge of the members of study sections and councils will in each case include all the latest information available in a particular specialty; consequently in view of the latter, recommendations for approval or disapproval appear generally to be the judgment of one or at best two peers. It was recommended that consideration should be given to revising the system for review and approval of grant applications in order to better cope with the large volume and high degree of complexity of the applications. This report also pointed up the fact that certain questions raised by the Wooldridge Committee still remained unanswered; namely, does the study section discussion modify a priority rating based only on reading the application prior to discussion; what determines which applications are site visited; does the site visit modify an original priority rating--in which direction; how is the quality of study section decision evaluated? (10)

In 1967, the American Medical Association's Commission of Research delivered its report.(11) Many of the recommendations of this Commission were addressed specifically to the American Medical Association. The Commission did conclude that the study section mechanism of NIH had been successful in identifying and supporting high quality research. The Commission recommended that membership on study sections should be rotated to prevent the development of an inbred, elite, decision-making establishment. The report also suggested that the primary consideration in selecting members of Advisory Councils should be professional attainment and the ability to make unprejudiced, statesmanlike judgments. The Commission also recommended the establishment of an advisory group for the Director, NIH.

The Fountain Committee Report in October 1967 (12) examined "The Administration of Research Grants in the Public Health Service." The report focused upon the principal research arm of the PHS, the NIH. (It should be recalled that the Committee had issued previous reports on this subject in 1961 and 1962.) The Committee was concerned about the gap in NIH research support between the "rich" and "poor" schools. One reason given was that a relatively limited number of institutions furnished the bulk of the PHS consultants and it was felt likely that these advisors reacted more favorably to the institutions and scientists that they knew best when evaluating project applications. Moreover, study section and council members were in a unique position to learn of research opportunities in their fields and to share with their colleagues an intimate knowledge of how the grant system operated. A second concern was the tendency, in PHS, to appoint a small group of individuals to multiple terms on councils and committees and the appearance of favoritism when these same individuals received substantial NIH grants. The Committee recommended that each council appointment be limited to one four-year term with members being ineligible for reappointment for a period of four years. It also recommended that consideration be given, in the selection of committee members, to balanced representation of geographic regions and educational institutions and, further, that to the extent possible, consultants should be drawn from among qualified scientists who are not themselves recipients of PHS grants.

In February 1968, the DHEW issued a response to the Fountain Committee Report.(13) There are, in particular, two sections of this 98-page report that are especially relevant to the interests of the current NIH Grants Peer Review Study Team. The first discussed the review system at NIH and its role in maintaining the high quality of research that was being supported. In the section on advisory committees, recommendations were made in regard to limiting the period of appointment of NIH advisors, geographical distribution, and to the development of standards to insure that scientists of high quality are appointed to advisory groups.

In 1970, the Council of Academic Societies of the Association of American Medical Colleges (AAMC) undertook to formulate "A Policy for Biomedical Research."(14) The Committee focused particularly on issues relating to the development of biomedical research manpower. The report supported continued emphasis on the individual project grant awarded through peer review as the primary instrument for the support of biomedical research, along with an expanded system of program project support addressed to problems of special relevance. The report included strong endorsement of peer review but stated that review mechanisms should be streamlined. There were, however, no detailed discussions or specific recommendations.

During the past several years, there have been increasing inquiries into the NIH peer review system. Some of these have followed upon the passage of the Freedom of Information Act (P.L. 89-487) and the Federal Advisory Committee Act (P.L. 92-463), and have stimulated a general review of advisory group activities and functions within the Federal Government. Within DHEW, additional controls and requirements have now been established with respect to the public advisory groups and these apply to the NIH public advisory groups. Thus, procedures for the technical merit review of scientific research proposals have been modified.

Among the studies and surveys that have led to such modifications, one must include that of the "Cooper Committee."(15) The report of this NIH Program Mechanisms Committee was issued in February 1973 to the Director, NIH. In this report, the Committee included seven recommendations bearing upon the grant and contract programs. Especially noteworthy is the recommendation "that NIH establish and refine the use of uniform policies and standard procedures by which its components define, develop, and implement programs, and initiate, review, select, and manage projects funded by contracts, grants, and other awards."(15)

In April 1973, NIH and the Health Services and Mental Health Administration (HSMHA) received an issue paper prepared by the Office of Management and Budget entitled "The NIH/NIMH Peer Review System."(16) The paper contained a generally accurate, brief description of NIH/NIMH peer review, including its statutory bases. In its identification of problems with the peer review system and its formulation of alternatives for improving the system, however, the paper displayed several serious misunderstandings and biases. Nonetheless, the report, and the commentary prepared by the Office of the Director, NIH, are of considerable interest. Both documents were considered and discussed in the July 1975 special oversight hearings of National Science Foundation (NSF) peer review (House Subcommittee on Science, Research, and Technology).

The requirement in the National Cancer Act Amendments of 1974 (17) for scientific peer review of applications for biomedical and behavioral research apparently resulted from the hearings before the Subcommittee, particularly the prepared statement from the AAMC. In urging peer review for contracts, the AAMC stated that (1) the use of nonfederal scientists to review grant applications for biomedical research projects to be funded by the Federal Government has assured a broad, nonfederal voice in the formation and implementation of national policy; (2) the peer review system which has been developed and utilized for NIH grants has assured a rigorous assessment of the scientific merits of research projects for which NIH grant support is being sought; (3) this process of scientific appraisal carried out by disinterested and expert scientists has resulted in the use of public funds only for the support of biomedical research which has met the highest standards of excellence; and (4) the process of peer review has been recognized as an effective mechanism in assuring maximum scientific returns for public investments in research grants.

In one of the few studies dealing with the effectiveness of decision-making in providing research support, Grace Carter of the Rand Corporation developed an original and rather ingenious, statistical method to examine NIH management and peer review decisions. Measures of research output and quality were developed and these were then used to explore trends in the quality of grant-supported research and the operation of the NIH peer review system. This 1975 report, entitled "Peer Review, Citations, and Biomedical Research Policy: NIH Grants to Medical School Faculty,"(18) is of considerable interest and value.

It is noteworthy that the NIH, in March 1975, submitted a report (19) to the then existent President's Biomedical Research Panel concerning the status of implementation of the recommendations of the Wooldridge Committee. The reader should recall that, in February 1965, the Wooldridge Committee (7), established by the President, made eighteen recommendations. Eleven of these were accepted in whole or in part and implementation was begun; seven recommendations were not accepted. Among the recommendations that related directly to peer review, there was a statement "that Advisory Council members owe their appointment to no higher Government level than that of the Director, NIH." The NIH noted that this recommendation had not yet been implemented. The Wooldridge Committee also recommended "that the study section procedure utilizing peer judgments should be preserved and strengthened and that the workload on individual study section members should be lessened."(7) The NIH status report indicated that this had been implemented initially but was affected by later changes. The workload of consultant reviewers has been seriously aggravated and the number of committees has been sharply curtailed. It is noteworthy that the average workload of an NIH Study Section has increased remarkably: from an average of 55 grant applications per meeting in 1969 to an average of over 90 applications per meeting in 1976.

OTHER REVIEW SYSTEMS IN THE FEDERAL GOVERNMENT

The NIH Grants Peer Review Study Team also undertook an examination of the review procedures in several other Federal agencies; this was conducted in the fall of 1975. In two agencies the review procedures appear to be especially relevant to the NIH. A brief summary of review procedures and policies in several other Federal agencies is given below.

I. THE NATIONAL SCIENCE FOUNDATION (NSF)

There are five separate directorates at the NSF and there are, as a consequence, five separate review systems. These are described in the June 1975 NSF Staff Study on Peer Review and Proposal Evaluation. In general, NSF utilizes three distinct options: panel reviews, mail reviews, and staff reviews. On the average, for all of NSF, a proposal is reviewed by 6.5 reviewers. There is no single list of NSF reviewers but lists of panel members are available. Forty-four percent of all competing proposals receive an ad hoc review only. Twenty-eight percent of all proposals are reviewed by a panel only. Some 28 percent of proposals receive both panel and ad hoc review. Some proposals submitted to NSF are reviewed solely by staff. These, however, are a distinct minority and represent such activities as conferences and workshops.

During 1974, the NSF received approximately 120,000 reviews. (In contrast, NIH reviews about 12,000 applications.)

In each of the NSF directorates, it is the program officer who is responsible for formulating a recommendation. The selection and the funding decision are made at a higher echelon. The program officer makes his recommendation to a section head but often this is referred on to a division head, assistant director, or even to the National Science Board. The Board reviews those proposals that are favorably recommended by a panel and that involve more than half a million dollars per year or a total commitment in excess of two million dollars. The Board does not review proposals recommended unfavorably.

Recently, the National Science Board passed a resolution indicating that full lists of reviewers should be published and that verbatim copies of reviews, without the reviewers' signatures, should be forwarded to the applicant investigator. NSF is currently informing reviewers that their verbatim comments will be made available to applicants.

Panels rate proposals that they have recommended favorably in five categories from excellent to poor and these roughly correspond to the NIH numerical rating system of 1 through 5. Staff provides feedback and reports to the panel at subsequent meetings concerning actions that have been taken on their panel recommendations. Although NSF staff members have not done so in the past, they will now prepare summary statements and provide resumes of the panel assessments and recommendations so that this information may be released upon appropriate request. A formal procedure for appeals is being developed at NSF but it is not expected that it will be used extensively.

Within the Biology Division, some 4,000 proposals are reviewed each year; approximately one-third are renewal applications. About 30 percent of all competing proposals are funded. Currently, some 35 percent of the funds available are used to award committed, non-competing continuation grants. Within NSF, it has been decided (administratively) that non-competing continuations should not utilize more than 60 percent of the available funds; this guideline has been set in an attempt to maintain flexibility for the support of new ventures. The maximum duration of grant support in the past has been limited to two years but it has now been extended to five. Therefore, the average duration of NSF grants is gradually increasing.

A visiting committee evaluates each NSF program area and the performance of the program officer, and provides advice to the Division Director and to the Assistant Director of the Foundation. It is of some interest to note that about 50 percent of the program directors at NSF are there on a rotational system while on leave from their parent institutions. These people are selected by the Division Director or the Assistant Director, NSF. The NSF staff believes that this system has worked well. Of the 24 scientists currently in the Biology Division, 12 are there on a rotational basis.

Within the Biology Division, the average research grant amounts to some $34,000 in total direct costs. There are, however, approximately 40 larger grants, somewhat similar to NIH program project grants, that range in size from $250,000-$500,000 per year; most are near the upper end of that range. The total expenditures for the Biology Division in support of research are 75 million dollars per year.

The average panel used by the Biology Division has eight members and there are 12 panels. The panels know in advance the amount of funds available for each program area and this information is taken into account in the proposal review sessions. Proposals that are reviewed are either funded or declined. Thus, there are no approved proposals that remain unfunded. This is a feasible and effective procedure for the NSF because its appropriation is obtained early in the fiscal year and it is therefore able to plan expenditures in advance.

The review panels meet three times a year, generally for two days. The average number of proposals reviewed per meeting is 100. Each proposal is, on the average, assigned to four reviewers. Site visits are conducted but not frequently. Travel funds are somewhat limited; oftentimes a site visit will be performed by staff members only.

Consultants are paid a fee of $75 per day but do not receive any remuneration for homework or mail reviews.

NSF panel members are appointed for a one-year period which may be renewed two times. Thus, most consultants serve a three-year term. In the Biology Division, at the beginning of each panel meeting a listing of the proposals and the ratings given by each of the panel members is distributed. Thus, with this information available, the greater part of the panel meeting focuses on discrepancies in ratings. The Program Director serves as chairman of the panel.

There are no formal deadlines for the submission of applications to NSF. In the Biology Division there is an average lapse of four months from the receipt of a proposal to the time that a decision is made and funding is made available.

The Division has a small contract program and issues "Requests for Proposals" in the usual manner. Contract proposals are reviewed by ad hoc committees.

There are four changes that the NSF staff would like to implement:

(1) to increase the number of panels for initial review;
(2) to decrease the panel workload to no more than 60 proposals per meeting;
(3) to perform more project site visits; and
(4) to have more staff available.

The NSF is planning to conduct several studies of its review processes. For example, the handling and fate of 1,000 applications will be studied. In addition, a survey (questionnaires and interviews) of several hundred applicants and reviewers will be conducted to determine their views of the NSF review system.

II. THE VETERANS ADMINISTRATION (VA)

The VA system for peer review of medical research is essentially an intramural system. There are some 135 stations in the VA system where research is conducted. Thus, this is basically a decentralized intramural medical research program. Seventy-five percent of the budget is devoted to that decentralized system whereas the remainder is centralized and involves cooperative clinical trials and career development awards. Centralized peer review is required if more than $25,000 per year is expended in a research project.

Initial review is conducted centrally by merit review boards and the secondary level of review is conducted by VA administrators. The membership and nature of the second level of review have been developed to reflect the intramural nature of the research effort: difficulties with staff and employees in field stations are avoided; orderly termination and phaseout support can be provided readily; and morale problems can be minimized or resolved.

Last year a total of $87.7 million per year was spent for medical research and $68 million of that amount was for decentralized research studies.

An attempt is made to fund all approved proposals to some extent. Furthermore, to preserve local allegiances and authority, funds are forwarded to the hospital for the support of the investigator's research but these funds can be reallocated by the local research committee.

The procedures for peer review have varied somewhat with time. Initially, boards were established and review was conducted centrally. There was then a brief period when there was total decentralization of the review and decision-making processes. For the past three and one-half years the current system has been in operation.

Currently, there are 14 merit review boards and each has 7-13 members. The boards are disciplined-based and they meet twice a year for one to two days. Members have three-year terms. Each board has at least one VA member, but overall, 25 percent of the total membership are VA employees. Many of the individuals serving on these merit review boards are, concurrently, NIH study section members. There are two cycles per year for review with December 1 and June 1 deadlines.

The 14 merit review boards are serviced by six staff members: three executive secretaries and three assistants. It is apparent, therefore, that one of the executive secretaries and one assistant serve five merit review boards.

A proposal may be reviewed by more than one review board at the same time. Twenty-five to 30 proposals are reviewed at each meeting. A numerical priority system is utilized with a score of 10 being the best and 50 the poorest. The average score is 27; any score numerically greater than 40 indicates that funding is most uncertain. Priority scores are derived by averaging individual scores voted by the members; they are not "normalized."

Each proposal is reviewed by at least three reviewers, one of whom must be a member of the board. Thus, many outside opinions are obtained. Each ad hoc reviewer is contracted by VA staff before the proposal is sent to him. It is of interest to note that the evaluations and opinions submitted by the reviewers are transmitted verbatim (but without the signature of the reviewer) to the hospital that submitted the proposal and thus to the applicant institution and the investigator. Each applicant receives at least three written evaluations prepared by individual reviewers along with the overall evaluation of the review board.

Approximately 35 percent of proposals are disapproved. The summary statements of the merit review board are written by a board member. Site visits by the board are not conducted frequently but if they are held they are generally small with a member of the VA staff of the central office always in attendance.

Recommendations made by the review boards are similar to those made by NIH Study Sections in terms of dollar amounts, duration of support, etc.

The review board meetings are closed although announcements are made in the Federal Register. Any public or scientific inquiries received are referred to the local VA hospital.

There is no formal appeals mechanism. It must be recalled that this entire review system is concerned with intramural research activities. Thus, a disappointed applicant must have the agreement of his local hospital research committee before he can submit a new or revised request to the central office. The local research committee often has many academic scientists from the medical school/university. For that reason local review is a significant phase of the activity.

Reviewers assisting by mail in this process are paid $50 for each opinion. Members of the merit review boards receive one day's compensation for their preparation time.

It should be noted that the peer review system described above is not universal throughout the VA. Cooperative clinical studies are assessed by an entirely separate procedure. They are reviewed and budgeted through a different mechanism. Similarly, the career development program of the VA is reviewed and funded through a separate set of procedures.

III. ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION (ERDA), DIVISION OF BIOMEDICAL AND ENVIRONMENTAL RESEARCH (DBER)

The major portion of the Division's support, about 80 percent, is for the National Laboratories; the remaining 20 percent is for the support of extramural projects. In 1975, this constituted approximately 20 million dollars.

ERDA supports solicited contract proposals submitted in response to a request for proposal (RFP) as well as unsolicited proposals. The latter are similar to NIH research grant proposals and procedures for their review will be described.

Unsolicited proposals may be submitted at any time during the year. Upon receipt, review is begun immediately. If handled normally, the review can be completed in three months or more rapidly, if necessary. Unsolicited proposals are referred to the appropriate Branch (currently there are five Branches), reviewed by the Branch Chief, and assigned to the technical staff representative whose scientific and technical expertise best matches the research proposal.

DBER uses a mail review procedure. A list of reviewers and their specialty areas is maintained and a general effort is made not to use the same reviewer too frequently. The technical representative sends the proposal to 3-6 outside reviewers and receives written reports from each. The consultants review for scientific merit only whereas the staff representative reviews for relevance to the mission and for budget considerations. The staff representative has the authority to reject the recommendations of reviewers; but if he does so, he must defend his action.

The staff representative's summary and the proposal are circulated to relevant technical staff within the Division for input from other experts, usually so-called "category teams" from each of several Branches of the Division who review the proposal. The proposal and summary report are then reviewed by the Research Committee of the Division, which is composed of the technical staff of the Division. This Committee meets weekly and the responsible staff representative presents a summary, recommendation, and the reviewers' opinions of each application. The Research Committee votes approval or disapproval and approved proposals are ranked for payment.

There is one budget for the Division. This allows for flexibility to shift funds where needed to support approved projects. If necessary, approved projects can be held until funds are available.

In 1975, the Division supported about 500 contracts and there are about 400 renewals yearly. Ongoing contracts are reviewed by outside consultants every third, sixth, and ninth year and the reviews are documented. New proposals over a specified dollar amount must be "site visited," usually by the staff representative, who must submit a written report prior to the initiation of the regular review.

IV. NATIONAL AERONAUTICAL AND SPACE AGENCY (NASA), OFFICE OF LIFE SCIENCES (OLS)

The NASA program is undergoing restructuring from a mission-oriented program to a problem-oriented program. Decentralization of funds and problem clusters are to be allocated to the three field laboratories. The procedure prior to the planned restructuring was to have all proposals received in the central office, then sent to the relevant field laboratory for prescreening prior to initiation of peer review which was conducted by the central office. A brief discussion of general review procedures will follow.

NASA carries out its mission via contracts and grants: contracts with industry, grants with universities and non-profit institutions. The nature of the project determines the choice of instrument. The review of unsolicited grant proposals will be described briefly as these proposals are similar to NIH investigator-initiated grant proposals.

Proposals are reviewed for scientific merit by panels convened quarterly. A contract with the American Institute of Biological Sciences (AIBS) provides for the management of panels, selection of members, conduct of review, and preparation of written reports evaluating the proposals. Membership on panels is on an ad hoc basis. Selection of reviewers is made as required to provide the expertise for the proposals to be reviewed at the specific quarterly meeting. There are deadlines for receipt of applications to meet the quarterly panel reviews. Although AIBS selects the panel members, there is input to the selection process form OLS. The panels review for scientific merit only, recommending approval or disapproval. If approval is recommended, the proposal is ranked for quality from 1 to 4. Intermediate rankings for quality often require additional information and/or negotiations with the applicant. OLS staff reviews proposals for program relevance. OLS staff prepares summaries and recommendations based on the two reviews. Funding decisions, made by OLS staff, are based on the scientific recommendations and mission relevance.

In 1975, it was estimated that approximately 3.5 million dollars was available for research grant support in biomedical research by this agency.

V. OFFICE OF NAVAL RESEARCH (ONR)

ONR supports mission-oriented basic research in four program areas. Proposals are reviewed by outside consultants convened on an ad hoc basis. ONR contracts with AIBS to select consultants and to conduct the panel reviews. ONR has no statutory requirement to provide peer review by outside consultants, but finds such reviews acceptable, and is generally guided by the recommendations. ONR may and frequently does recommend consultants to AIBS for the panels. The consultants review for scientific merit only. Proposals are rated on a rating sheet designed by the panel. With the information provided by the reviewers, ONR staff decides what should be supported, ranking proposals on the basis of relevance to the mission of the Navy.

Most contracts are for 4-5 years and there is about a 20-25% turnover. In 1975, ONR supported about 300 contracts including renewals, totaling approximately 15 million dollars. ONR does not anticipate an increase in funding or expansion of this program.

VI. UNITED STATES DEPARTMENT OF AGRICULTURE (USDA); COOPERATIVE STATE RESEARCH SERVICE (CSRS)

CSRS awards grants and a small number of cooperative agreements. Additionally, it has two formula grant programs and a discretionary special grant program. The special grant program is most comparable to the NIH extramural programs. In 1975, CSRS funded about 150-160 projects for a total of about 15 million dollars. CSRS anticipates about the same level for 1976 but may have a slightly higher budget approximating $19.5 million.

CSRS staff obtain outside expert opinions from "evaluators" for each proposal. Selection of experts is made by staff. The number of evaluators may vary according to the proposals. A standard list of ten technical and two "impact" criteria is used for evaluating proposals and a 0-10 ranking system is used. Conflicting recommendations of evaluators are resolved by further discussions with CSRS staff. Additional information may be solicited from the applicant, and additional evaluative opinions may be sought. Projects to be supported must fit program allocations as identified by the Department or by Congress.

Budget allocations in various program areas, criteria for review, and format for grant proposals are published in the Federal Register. Proposals are received within one month after announcement in the Federal Register and the review process proceeds immediately thereafter.

Rejected applicants are usually provided with a summary of the critical elements which may have accounted for the rejection.

The program of the Agricultural Research Service, USDA, was supported in 1975 by an allocation of approximately $250 million of which only $2 to 3 million was available for funding extramural projects. Grants are used to support and supplement the in-house mission, and only if by so doing, it will be more efficient and less costly than conducting the research in-house. No detailed review of this type of granting was made as this appeared to be research directed by in-house staff and more nearly approximated NIH contractual research.

REVIEW SYSTEMS IN OTHER COUNTRIES

The NIH Grants Peer Review Study Team has not had an opportunity to study foreign systems for the review of research proposals in a careful and systematic manner. However, many individuals on the NIH staff have had firsthand experience or contact with foreign review systems. It is significant that there is not available an up-to-date and comprehensive collection of information concerning these foreign systems. In our judgment, such an exchange of information among the research administrators who are primarily responsible for these functions would be useful; information and documentation concerning review philosophies and procedures should be distributed widely. This might be an appropriate activity for the Fogarty International Center to sponsor.

The members of the NIH Grants Peer Review Study Team have had available a 1974 report prepared by Dr. Kevin O'Brien of the National Health and Medical Research Council of Australia. The Australian Government had increased the amount of funds made available to the Council at that time and it was considered opportune for a study to be made of medical research administration in other countries. Dr. O'Brien, under a World Health Organization fellowship, visited those institutions "most experienced in research administration in North America, the United Kingdom and Europe..." His 156-page report entitled "The Organization and Administration of Medical Research" served as an important resource. (20) The Study Team is not aware of any other systematic study of peer review policy and procedures in various countries; such surveys would provide useful information.

In discussing the basic principles of central research organizations, Dr. O'Brien commented that "It was clear from my study that no perfect system has yet been developed for reviewing research grants--although the NIH system is about as just and as accurate as any procedure can be which depends in the last analysis on human judgment."

Furthermore, in describing the peer review system at NIH, the report states that "The procedures followed in reviewing what are known as traditional research grants were instituted first and constitute the most thoroughly established, the most rigorously followed, the easiest to understand, probably the most widely admired of the activities included in the external programs of the National Institutes of Health... The procedures worked out....constitute a very significant administrative invention..."

It is also noteworthy that this foreign biomedical scientist felt that "it may be well to point out that years of experience have given the scientific community in the United States a respect for the ability of the staff of the Institutes which it may not have had in the beginning. This respect and trust provides a firm foundation for giving a greater degree of responsibility to experienced staff members in the early stages of formulation and review of complex proposals in the new program areas."

CANADA

Since 1969, when the Government Organization Act was passed, the Medical Research Council of Canada has been a separate department reporting to Parliament through the Minister of National Health and Welfare. The Medical Research Council, however, operates outside the framework of the Department of National Health and Welfare. The Council differs from NIH and the Medical Research Council in the United Kingdom in that the Council does not have laboratories of its own and does not conduct research directly.

In Canada, voluntary agencies provide approximately 20 percent of the grant funds that support biomedical research; a modest amount of funds is available from Provincial Governments; the central Federal Government provides the major source of support.

The evaluation and review of research proposals, as conducted by the Medical Research Council, are very similar to the NIH referral and initial review group system. Heavy reliance is placed upon assessment by peer reviewers. Applications submitted to the Council are referred to one, and sometimes two, of its standing committees. Committee members who serve without remuneration are drawn from medical school faculties. Frequently, proposals are referred to outside reviewers who are not members of one of the Council committees. Each application, along with the outside opinions, is discussed in detail by the committee. The assessment includes scientific merit, significance of the proposed research, competence and background of the investigator, previous publications, and the appropriateness of the requested budget. Numerical ratings are assigned. The evaluations and ratings of all applications are reviewed by an Executive Committee and then forwarded to the Council for final action. Some particular aspects of these research grant awards are of special interest: under these awards principal investigators may not receive any remuneration and no funds are provided for overhead.

The staff of the Medical Research Council, the Secretariat, is responsible for the actual conduct of the review and approval procedures. Each year there are three competitions for project grant support. Approximately 800 applications may be received for each of these cycles. Senior staff of the Medical Research Council Secretariat, along with scientific consultants, assign each application to the most appropriate of the seventeen grants committees or, as noted previously, to more than one committee. The assignment of applications is done primarily "by title" of the project and takes into account the competence of individual committee members. In addition to assisting in the assignment of applications, the consultants also suggest outside reviewers to whom each application could be sent for comment. Shortly thereafter, each committee chairman receives a list of applications assigned to his committee and a list of suggested reviewers. The committee chairman may suggest reassignment to a different committee or changes in outside reviewers. The applications are then sent out for review. The committee chairman is also responsible for the assignment of each application to two or more members of his committee; they will conduct an intensive review of the proposal and will initiate the discussions at the committee meeting. Each committee member may receive betweeen ten and twenty such applications for in-depth review. Although each member of the committee does not receive a complete copy of every application, each member does receive an abbreviated version of every application assigned to his committee.

Application books are distributed to committee members approximately four weeks before their meetings in Ottawa. Each committee meeting lasts about two days but this depends upon the number of applications to be considered. Applications are discussed individually and in-depth. Each reviewer is required to assign a numerical rating to every application; after the meeting these ratings are averaged and listed in order of scientific merit for presentation to the Council.

The Council rarely alters the recommendations of the Grants Committees. The Council does take into account budget allocations, the abrupt withdrawal of research support, and other factors. Budget allocations are made by support mechanisms (fellowships, grants, developmental grants) several months before each competition. From time to time special projects are identified as priority areas, e.g., prenatal diagnosis of genetic diseases, therapeutic trial of human growth hormone.

In recent years the Council, the Secretariat, and the biomedical research community have been reexamining these procedures. Some have alleged that one grants committee is much more critical and rigorous than others. Committee members who have been transferred from one committee to another have apparently not noted such differences. At times the same application has been deliberately assigned to more than one Grants Committee—the differences in ratings and recommended budgets are said to have been minimal. Studies have been performed to test the effect of eliminating the highest and lowest ratings of committee members. Thus, repeated efforts have been made to test the objectivity and the discrimination of the Canadian peer review system. Concerns continue to be expressed, however, especially as funds are not available for the support of all meritorious research.

UNITED KINGDOM

In the United Kingdom, medical research is supported in several ways. The primary routes involve the universities and medical schools, the health departments, and the Medical Research Council. The Council has had a special role in supporting promising research projects and in fostering cooperation among the universities, the biomedical professions, and the Government. The impact of position papers such as the Rothschild Report is not entirely clear but increased "targeting" and mission orientation seem apparent.

The Medical Research Council has a variety of functions and has established several advisory boards and committees. Review procedures are administered by a Secretariat in the Medical Research Council headquarters. A health scientist administrator (Scientific Administrative Officer) and a committee secretary are assigned to each Grants Committee. The main support device is the project grant. These grants finance research on a well-defined project that can usually be completed within a three-year period. Other special types of grants for equipment, travel, etc. are also available. Most applications are received from medical schools, universities, and hospitals. Upon receipt, each application is reviewed by the health scientist administrator to be certain that the application is appropriate. Each application is then submitted to one of four Grants Committees depending upon the content of the proposal. The Committee is responsible for assessment of scientific merit, appropriateness of the budget, importance of the questions being investigated, etc.

The Secretariat staff assigns applications to individual members who review the proposal in-depth and lead the discussion. Each committee member, however, is asked to rate each application. Often opinions are obtained from outside consultants and referees and these are made available to committee members. Each committee member votes a priority score and these are subsequently averaged.

The scientific evaluation performed by each of the four Grants Committees is purported to be independent of the overall availability of funds. Thus, a deliberate attempt is made to attain uniformity and consistency based primarily upon considerations of scientific merit and opportunity. Applications that score very high are awarded without referral to a second body, a Research Board—unless they are unusually expensive. Similarly, proposals that are judged to be quite poor are declined immediately. Thus, in these circumstances, the Grants Committee has the final say in approval or disapproval of applications but in most circumstances applications are further reviewed by a Research Board.

Applications reviewed by the committees are interdigitated and listed in priority order and referred to one of two Research Boards. The Biological Research Board and the Clinical Research Board have responsibility for the allocation of awards among applications and they take into account factors such as cost effectiveness, other sources of support, recurrent expenses, and program relevance.

SWEDEN

The Swedish Medical Research Council was organized in 1945 as the governmental agency primarily responsible for the support of biomedical research. One section of the Council deals with general medicine while another, composed chiefly of armed forces representatives, deals with military medicine.

The major instrument for research support is the project grant. Proposals are submitted by individual scientists and these are reviewed for scientific and technical merit by discipline-oriented committees. There are eleven such committees and each committee has approximately five members. In certain areas, deemed to be of high program relevance, special groups or committees are established, e.g., alcoholism, drugs, and occupational medicine.

The scope of the activities of the Swedish Medical Resarch Council is a reflection of the country's sophisticated medical research status. Approximately fifteen research units are supported by the Council; in these units both tenured and non-tenured faculty appointments are supported. The Council also supports fellowships in basic and clinical research and much emphasis has been given to bridging these two areas of investigation. A rather substantial portion of Medical Research Council support is allocated to clinical investigation.

Although not directly related to peer review activities, it is of interest to note that the Council supports planning activities through the use of extramural consultants as well as information activities (equivalent to MEDLARS in the U.S.), animal resources, and studies leading to new modalities in prognosis and therapy.

SWITZERLAND

The Federal agency in Switzerland that supports biomedical research is the Swiss National Science Foundation. Actually this is a private foundation but it receives the major portion of its funds from the government. Aside from the biological and medical sciences, the Foundation also covers the humanities and physics. There is a Council for each area.

Within the Foundation, the Biological and Medical Sciences Council has twelve members, most of whom are university professors. The members serve four-year, rotating terms; the Council meets frequently—ten to twelve times per year. Most of the support of medical research is channeled through units that are attached to institutions. As at NIH, applications for support are reviewed by a review group system. In fact, the Council serves this role. Site visits may be conducted by members of the Council and it appears to be almost routine to request evaluations from outside reviewers. Although the size of the country makes the performance of site visits quite reasonable, other problems do arise: the availability of reviewers is limited and such reviewers are often competing for grant funds at the same time.

The Foundation has two deadlines each year for the submisison of applications; approximately 500 applications are received in the biomedical area each year. Each application is rated and then listed in "priority order" by the Council. Final decisions on grant applications are made by the Swiss National Science Foundation sitting as a committee of the whole. In general, projects are not funded for more than three years at a time. Grants may provide for salaries, equipment, and consumable supplies. Virtually all of the grantees are employees of universities.

A relatively modest amount of funds is reserved to support research professorships at the universities and a small budget is also provided for pre- and postdoctoral research fellowships.

CONCLUSION

Thus, it can be seen that most other U. S. Government agencies and many of the western countries have some sort of a review system which utilizes persons with specific expertise as reviewers although none of the systems is identical to the dual review system used by NIH.

STUDIES OF PEER REVIEW SYSTEMS

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THE GRANTS PEER REVIEW SYSTEM OF NIH

CURRENT PEER REVIEW SYSTEM - DESCRIPTION

In fulfilling its mission, one of the functions of the National Institutes of Health is to provide for the control of human disease through the support of biomedical research projects selected for scientific merit and relevance to health problems. Because of the magnitude, diversity, and complexity of the NIH research mission and the desire to obtain the best advice possible, NIH draws on the national pool of scientists actually engaged in research to assist and participate with NIH in the selection of the best research projects to implement a biomedical research program of the highest quality.

The NIH peer review system is based upon two sequential levels of review, referred to as the "dual review system." The first level involves panels of experts, generally established along lines of scientific disciplines, such as biochemistry, pharmacology, physiology, etc. The scientific panels, called Initial Review Groups (IRGs) consist of fifteen to twenty members and have, as their primary function, the review and evaluation for scientific merit of the research grant applications submitted to NIH for consideration of support. The NIH receives annually approximately 15,000 applications requesting support, which must be reviewed by these panels.

The second level of review is carried out by the statutorily mandated National Advisory Council/Boards 1/ of the Bureaus, Institutes and Divisions (BIDs) of NIH which award grants. It is the responsibility of the Council to review the appropriateness of the technical merit review recommendations made by the Initital Review Groups and to make a final review for scientific merit. The Council must also make recommendations as to program relevance and priority. With only very rare exceptions, the BID cannot make an award unless the Council recommends an application for approval. On the other hand, a BID is not required to award a grant simply because an application receives a favorable Council recommendation. The Council also has the broader function of advising on the overall program of the particular BID as well as the legal responsibility for recommending which projects are to be awarded.

The dual review system permits separation of the assessment of projects for scientific and technical merit from subsequent policy decisions concerning programmatic, scientific areas in which projects will be supported and the level of resources to be allocated to those areas. By such a separation, a more objective evaluation is obtained than would result from a single level of review. The dual review system, because of its advisory character, provides the responsible

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1/ The National Cancer Institute and the National Library of Medicine have Advisory Boards. All of these advisory bodies will be referred to as Councils.

federal officials with the best advice possible in regard to both scientific and societal values and needs. A brief description of the procedures involved in NIH peer review follows.

Research grant and all other grant applications prepared by investigators are submitted through their institutions to the Division of Research Grants (DRG), which serves as the central receipt point for all of the applications of the BIDs. The DRG reviews each application for relevance to the overall NIH mission and, if acceptable, assigns it to the appropriate IRG for scientific merit review and to the appropriate BID for consideration of an award.

The IRGs meet three times yearly to review the applications assigned to them. IRGs are composed primarily of nonfederal scientists selected by NIH for their competence in the particular scientific areas necessary for the critical review of applications. In advance of the meeting, the Executive Secretary of the IRG studies all of the applications assigned to his/her group and obtains any additional information deemed necessary for the review from the principal investigator or applicant-institution. Each application is assigned to two or more members of the IRG, each of whom prepares, in advance of the meeting, a detailed critique of the applications assigned and who lead the discussion of these applications at the IRG meeting. Six to eight weeks in advance of the meeting, every member of an IRG receives a complete set of the applications scheduled for review at that particular meeting. In addition to the applications for which they have been designated as discussion leaders, the members are asked to become familiar with the remaining applications. During the six to eight week period prior to the meeting, the members of the IRG often contact the Executive Secretary for additional information, if needed, for the review of a particular application. In certain instances, this information can be obtained only by visiting the investigator(s) at his/her institution. The specific details of a project site visit have been described by Merritt and Eaves in their article entitled "Site visits for the review of grant applications to the National Institutes of Health: Views of an applicant and a scientist administrator." (1)

Each application is discussed individually at the IRG meeting. It is the responsibility of the IRG to review applications on the basis of technical merit and scientific significance, which includes: 1) an assessment of the importance of the proposed research problem; 2) the novelty and originality of the approach; 3) the training, experience and research competence or promise of the investigator(s); 4) the adequacy of the experimental design; 5) the suitability of the facilities; and 6) the appropriateness of the requested budget relative to the work proposed. The recommendation of the IRG is made by majority vote of the members. If recommended for approval, the application is assigned a technical merit priority rating by each individual IRG member, "1" being the most meritorious and "5" the least meritorious. The arithmetic average of these individual scores is multiplied by 100 and this numerical rating becomes the IRG's "raw" priority score. An IRG may also vote to recommend disapproval of an application or to defer it for further information and later recommendation. Following the meeting a summary statement is prepared for each application recommended for approval or disapproval; the summary ["pink sheet" in the case of DRG initial review groups (study sections)] contains the recommendation, the priority score, if the application has been favorably recommended and a summation of the reasons for the IRG's recommendation. This statement is forwarded to the appropriate BID for the next level of review—consideration by that unit's National Advisory Council.

In general, the National Advisory Councils also meet three times yearly for approximately three days, and each Council member receives, in advance, copies of all summary statements releveant to the BID for which they are advisory. Copies of the application are also available to the Council members, if specifically requested. The membership of the National Advisory Councils is set by law. They usually consist of twelve or more members, including some who are scientists and others who are lay community leaders interested in health areas relevant to the program areas of the particular BID.

Following the above actions by the various peer review gorups, the BID staff makes its program decisions on funding. After the investigator is notified of the recommendation of the National Advisory Council, he/she may request the BID to send a summary of the comments which led to the action taken on the application. In the case of disapproved applications, or approved applications which are not awarded, these comments can be very helpful if the investigator wishes to submit a revised application. The procedure to be followed in submitting a revised application is described in the instructions which are included in the research grant applicaton kit.

It is interesting to note that the cost of this review process, from the time an applicatoin is received to the making of an award, is a very small percentage of the amount of funds awarded. In fiscal year 1976, approximately $1.4 billion were awarded for competing and noncompeting applications, including indirect costs. The cost of the peer review process is approximately $15,800,000. This represents about one percent of the total funds awarded.

A detailed description of the peer review system is provided in Appendix C.

References

1. Merritt, Doris H., and George N. Eaves. Site Visits for the Review of Grant Applications to the National Institutes of Health: Views of an Applicant and a Scientist Administrator. Fed. Proc. 34: 131-136 (1975).

SEPARATION OF REVIEW AND PROGRAM FUNCTIONS

The Grants Peer Review Study Team unanimously and strongly endorses the principle of separation of review and program staff functions at NIH. In some respects it has been in effect at NIH almost since the beginning of the extramural grants program. The respect and reputation of the Initial Review Group or "'study section' apparatus," under the jurisdiction of the Division of Research Grants, is a testimonial to this principle.

The Division of Research Grants (DRG) conducts initial scientific and technical merit review of regular research grants* or the 11 NIH institutes, the National Library of Medicine, the Division of Research Resources, and several other segments of the PHS. It is a separate organizational entity within NIH, subservient to none of the BIDs it services. Organizationally, it is accountable only to the Director, NIH. Implicit in this arrangement is the fact that the review of regular research grants is under the management of separate DRG professional staff which has no responsibility for the management of grant programs. Funding decisions are made at the program level within the BIDs.

There are philosophical and practical reasons for this arrangement. The arrangement provides a buffer to prevent emotional or political considerations from entering into the decision-making process. Centralized peer review offers the advantage of greater efficiency in utilizing consultants to review the very large number of applications received each year. Unnecessary duplication of consultant manpower is avoided because applications can be clustered into circumscribed areas of science. Moreover, having the review apparatus centralized in one organizational locus allows for monitoring and surveillance and fosters the development of uniform review practices and procedures.

The NIH has a wide variety of grant activities. Whereas the regular research grants, fellowships, and the research career development award applications are reviewed by the DRG study sections, applications for many of the other grant programs such as program projects and centers are reviewed by the BIDs. Over the past few years, there has been a trend within the BIDs to emulate the DRG system. Thus, the National Heart, Lung, and Blood Institute has created its own peer review system to evaluate the many special grant applications. Other institutes are attempting to do the same. For example, the National Cancer Institute has a centralized peer review system for the review of program project and center grant applications. This pattern is gaining momentum at NIH because of the growth of certain programs and the recognition that the DRG model offers many advantages. The DRG model is especially attractive since the reviews being conducted in the institutes involve support mechanisms which have been subject to some criticism in the past, including large grants which are complex, involve large amounts of money, and must be subjected to thorough peer review to match that carried out by the study sections.

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*The term "regular research grants" is used to designate investigator initiated research grants coded as R01s, as distinguished from program project, center, or other special, multipurpose type of grants.

Because of the very special nature of these Institute initiated programs, it is important that there be good coordination, good planning, and good communication among Institute staff to accomplish effective, critical, and reliable review. It is important that staff carrying out reviews understand the objectives and the goals, not only of the Institute but of the particular initiative under consideration; they must also be thoroughly conversant with review policies and procedures. This review responsiblity should be placed in the hands of a staff that can apply uniform standards of peer review for the support mechanisms under its jurisdiction. At the same time, the review staff must be privy to program plans as they develop and mature in order to fully grasp the intent and background of the initiatives. It is equally important that program staff responsible for developing the initiatives and managing the awards and contracts after they are made, be given the opportunity to explain such initiatives to review committees. What emerges from this brief portrayal is a dichotomy of professional staff functions: the function related to review and the function related to program management. As in the case of the DRG-BID relationship for the regular research grants program, the professional staff functions within a BID should be kept distinct and separate.

In addition to some of the reasons already cited, one of the major advantages of this separation is to avoid prejudice and partiality or circumstances in which there may appear to be undue emotional or intellectual commitment to a particular approach. For example, even the most well-intentioned and virtuous program manager is suspect when he authors a Request for Application, selects the consultants to review the responses, chairs the review meeting, tallies the votes, writes the summary statements, selects the applications to be awarded, and serves as the program administrator. The Study Team believes that such situations must be prevented; the credibility of award decisions must be carefully guarded. To this end, the establishment of a peer review system within an Institute, in the hands of a professional staff detached from financial involvement in program development and management, offers the best preventive remedy to insure the continued well-being and integrity of initial peer review. In order to maintain confidence in the system and to assure adherence to the principle of separation of review and program staff functions, continued overview is necessary at both the BID and NIH levels.

The separation of review and program staff responsibilities has been demonstrated to be not only workable but wise. It has increased the objectivity and the credibility of the entire peer review system and this, in turn, accounts for its durability and the confidence in the system that presently exists.

THE ROLE OF PEER REVIEW IN DECISION-MAKING BY NIH

Although the primary focus of its efforts has been on the assessment of scientific and technical merit, the Study Team believes it is useful to reflect upon the role of peer review in the broader contexts of decision-making at NIH. Since the very inception of extramural programs at NIH peer review processes have often played a central role in many phases of decision-making. These processes have been utilized in program reviews, in determining program relevance and priorities, in setting or resetting program balance, and in the planning and evaluation of programs.

The Initial Review Groups (IRGs) take part in one of the first and probably the most important steps of the aforementioned activities: the identification of projects that are meritorious and worthy of support, using scientific merit as a primary basis for judgment.

The Institute Advisory Councils and Boards play a major role in considerations having to do with program relevance and program balance. They give advice and guidance in the identification of projects which will provide for a balanced program and which will bear significant relevance to the program objectives and missions of the specific Institutes. In making their judgments and recommendations, the Councils are mindful of the funds available to the Institutes, and the recommendations they make are based on their best judgment for the appropriate use of available funds.

On a continuing or intermittent basis, individual consultants or groups of consultants are assembled as task forces, advisory committees, and commissions, and (using such mechanisms as workshops, symposia, or regularly planned meetings) they provide useful information and suggestions to Institute staff on program planning and program evaluation. These consultants provide advice and counsel regarding research program and training areas where such information is needed, and they assess the appropriate timing for the initiation of programs to translate research knowledge into clinical application.

Traditionally, NIH has always relied heavily on the input received from its advisory groups. Although program decisions on funding, whether for program balance, program relevance or priority, or for other considerations are the ultimate responsibility of staff, nevertheless, the good judgment provided by members of peer review groups in their capacities as IRG members, Council members, or ad hoc consultants has formed a basis for a close partnership and trust between consultants and staff.

Strenuous efforts are made to insure that consultants of the highest quality and capability are selected. Yet there is a need to insure geographic and institutional balance as well as female, minority, and youth representation. It is also recognized that the individuals selected as IRG and Council members frequently compete for NIH funds to support their own work; this is a natural consequence of a review system that rightly places such importance on selecting reviewers of outstanding competence. The advice of such experts is considered essential and, therefore, steps have been taken to avoid conflicts of interest.

Some of the problems confronting advisory groups, and which affect their recommendations in review, have to do with their own perceptions of the appropriate balance between targeted and basic research, the balance between funds to be allocated for contract versus grant-supported activities, and the balance between project support or other support of large programs or centers. For example, in one Institute, the Council has the specific, legislatively mandated responsibility to provide advice concerning the percentage of funds to be used for contract supported research. In recent years, the Advisory Councils and Boards have become very much concerned with the balance of funds available for traditional investigator-initiated research projects and that available for the larger mechanisms of support, i.e., program projects, research centers, and other special purpose, multidisciplinary grants. In some instances they have recommended a ceiling for each type of support. Thus, the impact of the various advisory committees on such decisions is increasing. The changing character of the times, the limited availability of funds, considerations of accountability, the increased participation of public members, and the increasing visibility given to advisory committee recommendations will continue to contribute to a changing pattern of decision-making.

With all of these factors and influences weighing upon NIH decision-making, the assessment of quality and merit must be maintained as the consideration of overriding importance.

PERCEPTIONS OF THE NIH GRANTS PEER REVIEW PROCESS

PERCEPTIONS OF THE NIH GRANTS PEER REVIEW PROCESS

I. INTERACTION OF STUDY TEAM WITH THE SCIENTIFIC AND LAY PUBLIC

From the inception of the activies of the Grants Peer Review Study Team (GPRST), it was clear that there was a need to obtain the perceptions of individuals other than NIH staff about the NIH peer review system. Opinions were actively solicited from several groups namely, the scientific public, the general public, and those who participate in the peer review process as members of Initial Review Groups and Advisory Councils. The interactions are summarized below:

1. Letter Responses from the Scientific Community and the Public

A formal announcement of the establishment of the NIH-GPRST appeared in the August 8, 1975, issue of the NIH Guide for Grants and Contracts and in the September 4, 1975, issue of the Federal Register (Appendix A). Included in the announcements was a statement that the Study Team would be pleased to receive written comments, views, and relevant information from the scientific and general public concerning their perceptions of the NIH peer review system. Subsequently, in order to increase the response, a new call was made at the time the Study Team announced that it would hold open public hearings. This new call was announced in the December 8, 1975, issue of the Federal Register. In addition, a memorandum was mailed to a total of 30,000 grantee-investigators, disapproved applicant-investigators, those whose applications were approved but not funded, potential investigators, scientific associations, public interest groups, key officials of interested institutions (including minority and small schools) scientific women's organizations, scientific newsletters, and all others on the mailing list for the NIH Guide for Grants and Contracts (Appendix B). Within several months, approximately 1,500 letters were received. The letters came from a wide variety of individuals. Many respondents identified themselves as grantees, as "disappointed" applicants whose requests had been disapproved or approved but not funded, or as present or former Advisory Council or Initial Review Group members. Most spoke for themselves while some indicated that their letters represented the views of a group or a specific organization.

Although many individuals strongly endorsed the present NIH review system and pleaded that it not be "tampered with", many others were critical or made suggestions for specific changes. The letters expressed the respondents' views on a broad range of issues, and a great variety of subjects were discussed. However, review of the 1,500 letters indicated that four issues were discussed most frequently:

1. The selection of initial review group members, including concerns such as bias and cronyism.

2. Concerns over the impact of the Freedom of Information and Privacy Acts on the quality of scientific review.

3. The quality and availability of summary statements.

4. The need for a mechanism to permit appeals, in regard to the recommendations of peer review groups, as well as assignments of applications to Initial Review Groups and/or Institutes.

Other issues were addressed, but to a lesser extent. These included the quality of the review of large grants, the workload of Initial Review Groups, release of priority scores, and problems of support for minority and women investigators.

Other important elements expressed in the letters were suggestions for improving or modifying the current NIH review system. Many suggestions were presented in detail, indicating concern based on knowledge and experience and were worthy of consideration.

In reading the letters, the GPRST members were impressed by the serious and thoughtful nature of the opinions expressed. The perceptions of the Ctudy Team were considerably enhanced by the review of the letters, and its subsequent deliberations were influenced by the views offered therein.

From a careful reading of the letters, it became clear to the Study Team, however, that many statements made, in good faith, reflected a lack of knowledge of the NIH peer review system as well as of the specific steps involved in processing a grant application. For this reason, it became especially important to prepare a detailed description of the entire peer review process as part of the activities of the Study Team (Appendix C).

So that NIH may fully benefit from comments contained in the letters, a detailed analysis of them is being prepared by non-NIH consultant-contractors. The contents of the letters will be indexed by subject and then summarized. Relevant and representative excerpts will be quoted. All suggestions for changing or revising the current NIH peer review system will also be indexed and summarized. Background information on respondents which will be helpful in evaluating the comments-their status as approved or "disapproved" research grant applicants, their experience on NIH peer review groups, and other factors-will be presented, if available. This study is currently in process and results are expected to be available in late 1977, and will be included in Phase II of the NIH Grants Peer Review Study Team Report.

2. Open Public Hearings for the Scientific and Lay Community

The Study Team recognized the value of the letters in providing input from the community but it felt that more direct interaction was also desirable. Accordingly, it was agreed that open public hearings would be an important and very useful means of eliciting information and recommendations from concerned scientists and others affected by the grants peer review process. Public hearings were held as one day sessions during February 1976 in government facilities in each of three geographic locations. The meetings were held in Chicago, Illinois, San Francisco, California, and Bethesda Maryland. The Study Team designated a panel of its members to attend all three hearings. The panelists routinely asked the speakers questions designed to elicit clarification of of, or elaboration upon, key points but made no attempt to debate issues with those testifying or to correct clearcut inaccuracies in the written and oral comments offered. Twenty to thirty formal 10 minute presentations were heard at each hearing. However, additional speakers were heard from the floor, and the panel remained in session until all comments were received. Despite the limited number of presentations (69), the Study Team felt that much useful information was gained. A list of speakers, their institutional affiliations, and transcripts of the Hearings testimony are available in the files of the GPRST. Copies of the transcripts may be obtained by addressing the Freedom of Information Officer, Office of the Director, NIH, Bethesda, Maryland 20014.

The speakers were advised in advance that the GPRST was interested in their views on the following topics:

1. Adequacy of the total review system, e.g.,
   a. The effectiveness of the system in serving and responding to societal needs and expectations for biomedical research on disease-related problems.
   b. The effectiveness of the system in assisting in maintenance of a strong, high quality national biomedical science base.
   c. The extent to which the system assists in meeting the best standards of public accountability for expenditure of public funds.

2. Adequacy of the initial scientific review.

3. Adequacy of the Council review.

4. Adequacy of the priority rating system.

5. Impact of the Privacy Act of 1974.

6. Impact of the Freedom of Information Act, as amended in 1974.

7. Impact of the Federal Advisory Committee Act.

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8. Recommendations as to how the present Grants Peer Review System can be improved.

Each speaker was asked to present a written summary, or a general outline or statement in full, in advance of the hearing.

Examination of the testimony presented at the hearings indicated that the speakers represented 55 different institutions and 11 organizations. Some individuals traveled a considerable distance at their own expense to attend the hearing at which they were scheduled to speak. An effort was made by the Study Team to attain a geographic spread of institutional representation among the speakers. Generally, however, the speakers were accepted on a "first come, first served" basis, as their requests were received in the GPRST office. A special effort was made, however, to encourage presentations from minority schools and, indeed, four such institutions were represented. The president of a women's scientific organization responded with the views of women scientists. Two legal officers presented the views of their organizations relating to legal aspects of the peer review system, and other speakers addressed these issues as well.

A number of speakers expressed total support for the NIH system, but others spoke to aspects of the system about which they had some concern. In general, the speakers who expressed concerns over aspects of the peer review process addressed the same issues addressed in the letter responses: (a) the process by which members of IRGs and Advisory Councils/Boards are selected, including related comments regarding cronyism and the "buddy" system, (b) the impact of the Freedom of Information and Privacy Acts on the quality of scientific review, (c) the quality and availability of summary statements, and (d) the need for a peer review appeals mechanism. Several speakers spoke eloquently about the need to support young investigators, and the need to support unorthodox or high risk research. A few speakers presented interesting suggestions for changing certain aspects of the peer review system such as the creation of a permanent office at NIH to plan and conduct experiments in regard to the peer review process.

It is important to remember that the hearings were held to obtain the views of those who participate in, or are otherwise affected by, the peer review process so that the perceptions of the external community could be reflected in the thinking of the Study Team. This was also the case in the letter responses from the external community. Similarly, it became clear from the hearings that there are misconceptions and misunderstandings thoughout the external community concerning the operation of the NIH peer review system, and it became doubly clear that not only was a description of the process necessary, but that it should be widely disseminated.

The testimony presented at the hearings is presently being analyzed and evaluated in detail in a manner similar to that for the letter responses, and will be included in Phase II of this report to be completed in late 1977.

3. Survey of Initial Review Group and Advisory Council/Board Members

The third group of individuals from whom comments and opinions were sought by the Study Team was made up of those who participate in the peer review process as members of Initial Review Groups and Advisory Councils. This was accomplished by means of a survey questionnaire designed and developed by a subcommittee of the parent Study Team with the aid of a consultant survey research specialist and other non-NIH consultants. The purpose of the survey was to obtain assessments of the existing grant application peer review system and suggestions for its improvement from active participants in the system--the current members of NIH grant review groups and advisory councils. More specifically it was planned that the survey focus on the reactions of the group members in three major areas:

1. Evaluation of the current NIH grant peer review system.
2. Assessment of the impact of recent changes and of potential future changes on the quality and efficiency of the NIH grants peer review system.
3. Suggestions for improving the existing system.

Four other basic decisions were made regarding the survey:

1. The anonymity of all respondents was to be preserved in order to obtain valid answers,
2. The respondents would be encouraged to supply comments in order to expand their responses, or to include concerns omitted from the questionnaire,
3. The survey would include all current members of the peer review system and not be limited to a sample of such members, and
4. Only one survey instrument would be developed even though not all questions would be equally applicable to each of the three types of review groups surveyed — the Division of Research Grants Initial Review Groups, the BID Initial Review Groups, and the National Advisory Council or Board of each BID.

Analysis and Evaluation of the Survey of Initial Review Groups and Advisory Councils

A detailed report of the statistical findings of this analysis appears in Supplement A. A summary of the major findings of the survey is attached (Tab A). Additionally, a detailed comprehensive report of the survey, including analysis and evaluation of the comments section, is being prepared and will be available at a later date.

A total of 1,354 questionnaires was distributed to 12 Advisory Councils/Boards*, 51 DRG-IRGs, and 24 Institute IRGs during their meetings in November-February 1976. The questionnaires were given, not only to the regularly appointed members of the peer review groups, but also to liaison members representing Federal agencies and to those ad hoc consultants attending those meetings whom the Executive Secretary considered to be knowledgeable concerning the review process.** The overall response rate was exceptionally high, 94%, attesting to the interest and cooperation of the peer review group members.

In examining and commenting on the survey responses, the differences in mission and composition of the Initial Review Groups and the Advisory Council/Boards must be kept in mind. It should also be remembered that the DRG-IRGs generally review the traditional investigator-initiated research grant applications; the Institute IRGs generally review the special purpose type grant applications, usually the large program project or center grants, and other types of grants submitted in response to specially announced program needs of an Institute. Another fact to be borne in mind is that the IRGs are the "producers of a product," namely, a summary statement ("pink" sheet) and a priority score for the application, whereas the Advisory Councils/Boards are the "users of the product." Such differences in function may well lead to different appraisals of the adequacy of a particular product or NIH procedure.

Approximately one-half of the 1,274 initial review group and National Advisory Councils/Boards members who completed the 1975-76 Peer Review Survey questionnaire also wrote one or more remarks in the ample space provided for comments. A slightly higher proportion--51 percent--of National Advisory Council/Board members than of initial review group members--49 percent--made comments.

Because it was judged important to utilize fully the comments and suggestions made by this experienced and knowledgeable group, the Survey Subcommittee of the Grants Peer Review Study Team decided to sponsor an in-depth analysis. This work is currently in its initial stages and will be completed in 1977. However, in order to enable the Study Team to benefit from the comments during its deliberations, two major projects were undertaken:

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*Members of the Board of Regents of the National Library of Medicine were not surveyed.

**Thirteen percent of the respondents were liaison members or special reviewers.

1. The comments were transcribed to a computerized data base and the resultant computer listings of the full text of each comment, categorized by applicable survey question, were circulated.

2. Four analytical reports on issues of special interest to the Study Team were completed. These reports are presented in Supplement B.

Tab A, as mentioned above, presents the major findings of the statistical analysis of the survey.

MAJOR FINDINGS

The current NIH system for the review of research grant applications was overwhelmingly endorsed by those individuals who were members of NIH review or advisory groups at the time of the survey. More than one-half characterized the system as a whole as "excellent" and over 95 percent rated it as either "excellent" or "good." Equally high ratings were given the general fairness and lack of bias found in the operation of the system.

The general satisfaction with the current NIH review system was reflected in the lack of enthusiasm expressed for recent changes and for potential future changes in the system arising from Congressional and public concerns with the openness of Government processes. Of 16 such changes, only four were perceived by more than half of the review group members as having either a "very favorable" or a "favorable" effect on the quality and efficiency of the NIH grant review system.

Even less enthusiasm was shown for the 20 suggested improvements listed in the questionnaire. One suggestion--recommending a study on how to reduce the time lag between application and final NIH action--received the endorsement of three-fourths of all review group members. None of the other 19 suggested changes received the support of a majority.

The members of the DRG Study Sections were generally the most favorably disposed of the three types of review groups toward the current NIH review system and the members of the National Advisory Councils/Boards were generally the least favorably inclined. Even so, about 90 percent of the National Advisory Council/Board members designated the overall NIH review system and its lack of bias as excellent or good. The greater degree of satisfaction of DRG Study Section members was also evidenced by the fact that they were less favorable than both the other two review groups in their responses to 14 of the 20 suggested improvements listed in the questionnaire.

The survey findings showed that members of the three types of review groups varied in certain characteristics and that some of these differences reflected differences in functions among the groups. On the average, DRG Study Section members had the least prior experience with the NIH peer review system, had the greatest proportion engaged currently in research activities or as principal investigators on NIH research grants, had the smallest proportion in clinical activities, were the youngest, and had the smallest percentage of women members. Members of the National Advisory Councils/Boards differed the most from DRG Study Section members in many characteristics while Institute IRG members frequently fell between the two other groups. In some instances, the characteristics of Institute IRG and National Advisory Council/Board members were similar--over one-third were engaged in clinical activities and one-fourth were women (Tables 4, 5 and 6).

Delays occurring in recent years in making appointments to National Advisory Councils/Boards were reflected in the finding that almost one-half of the members of these advisory groups were serving the first year of their current appointment. In contrast, Institute IRG members were relatively evenly spread among the four years while about one-third of DRG Study Section members were first-year appointees (Table 4).

Assessment of the Current NIH System

All parts of the NIH review system did not receive the high level of approval elicited by the questions on the overall system and its general fairness. Frequently, responses on specific features were less favorable than the answers given on more general aspects. Nonetheless, over one-half of the review group members assigned a rating of either excellent or good to the 48 questions on the current system which are appropriate for this kind of an analysis.[1] That is, each aspect of the current NIH review system covered by one of the 48 questions received a favorable rating from more than a majority. In fact, 33 of the 48 questions on the current system were rated favorably by at least 80 percent of the review group members. The greater satisfaction of the DRG Study Section members is clearly evident, as is the relatively more critical assessment of the National Advisory Council/Board members:

Distribution of questions by the proportion of members responding excellent/good or the equivalent

Percent of members responding favorably	Number of questions			
	All groups	Initial Review Groups		National Advisory Councils/ Boards
		DRG Study Sections	Institute	
Total	48	48	48	48
Under 50 percent	0	0	0	0
50 to 59 percent	1	1	0	1
60 to 69 percent	2	3	6	10
70 to 79 percent	12	9	11	8
80 to 89 percent	14	11	16	20
90 percent and over	19	24	15	9

Persons accepting appointments and actively participating in the NIH research grant review system may be expected to be favorably disposed toward that system as well as knowledgeable about its policies and procedures. In analyzing the ratings [/2] assigned by the review group members to specific aspects of the system, it is difficult to discern negative reactions. With the exception of three questions, at least 70 percent of the respondents judged the current system as either excellent or good. However, it is possible to group the replies by the differing levels of support given specific parts of the current NIH research grant review system (Table 1).

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[1] Seven of the items in Part II of the questionnaire were omitted from this analysis--Question 4n; Questions 10b, d, f, h and k; and Question 11.

The strongest endorsements, those aspects of the current system approved by at least 90 percent of the review group members, included:

. . . Lack of general bias in the NIH grant peer review system as well as in the performance of NIH staff, peer review group members, and the peer review system procedures. The responses of DRG Study Section members were consistently the most favorable and those of National Advisory Council/Board members consistently the least favorable (Table 7).

. . . Lack of bias against minorities, young investigators or women in the review of applications in recent years. Again, the DRG Study Section members were the most favorable and the National Advisory Council/Board members the least favorable. More bias was perceived on the other side of the coin--favoritism toward these groups, particularly young scientists (Table 7).

. . . The overall adequacy of the current NIH review in general and for the initial review of traditional research project (R01) grant applications (Table 8).

. . . The adequacy of the current review performed for the scientific and technical quality of new grants and for the capability of research investigators (Table 9).

. . . The value of site visits to the review process and the quality of site visits. In a shift from their usual ranking, Institute IRG and National Advisory Council/Board members were more enthusiastic about the value of site visits than the DRG Study Section members who conduct such visits much less frequently than Institute IRG members as part of their reviews (Table 10).

. . . The performance of review group members as measured by the quality of the discussion of applications and their behavior during the review process. Once more, the DRG Study Section members were the most favorable (Table 13).

[/2] The questions on the current system permit the selection in most instances of one of the following: excellent, good, fair, poor, very poor, or no opinion. For some questions on bias, the choices are: none, insignificant, moderate, significant, very significant, and no opinion. Percentages are computed on a base which excludes "no opinion" and all nonresponses to that question.

. . . The scientific and technical members' qualifications and performance. The assessments made by the members of the National Advisory Councils/Boards, which include lay or public members, were less favorable than the opinions of the members of both initial review groups which are entirely composed of such scientific and technical members (Table 13).

. . . NIH staff qualifications and performance in administering the peer review system, both the executive secretaries of the initial review groups and all other staff (Table 13).

At the other extreme, the least support was given two of the current NIH restrictions governing applicant notification. The lowest rating (56 percent favorable) was given the present requirement which prohibits informing the applicant of the priority score assigned by the initial review group and the third lowest score (69 percent favorable) was given the requirement which delays informing the applicant of the overall initial review group recommendations until completion of the final review by the National Advisory Council/Board (Table 1).

The weakest endorsements, those approved by less than 80 percent of all review group members, included:

. . . Some bias toward "cronyism" although rejected by over 70 percent of all review group members who perceived no signs or only insignificant signs of such favoritism in the review of applications (Table 7). About 20 percent reported observing moderate amounts of such a practice and almost 10 percent reported observing significant or very significant amounts. Sharp differences existed in the perceptions of "cronyism" among the review groups. Only 5 percent of the DRG Study Section members perceived significant or very significant evidence of "cronyism" compared with 12 percent of the Institute IRG members and 24 percent of the National Advisory Council/Board members. Within each review group, women members and the younger scientists were the most critical.

. . . The review of program project and center grant applications was judged less adequate by all three types of review groups than the highly-rated initial review of traditional research project grants. However, the degree of satisfaction varied among the groups. Over 85 percent of the members of the Institute IRGs, who perform these reviews and are most intimately familiar with the process, rated such reviews as either excellent or good. Almost as high a proportion of National Advisory Council/Board members, who use the reviews in their deliberations, indicated satisfaction. The lowest rate of approval--73 percent--was by the DRG Study Section members, many of whom may not be familiar with this type of review as is evidenced by their unusually high 35 percent no opinion/no response rate on this question (Table 8).

TABLE 1. ASSESSMENTS OF THE CURRENT NIH RESEARCH GRANT REVIEW SYSTEM

Grouped by the proportion of all review group members responding
excellent/good or the equivalent

QUESTIONS ON THE CURRENT SYSTEM (PART II OF QUESTIONNAIRE)	PERCENT
A. 90 percent or more responding excellent/good (19 items)	
Q1. How adequate is the review currently performed for:	
a. The scientific/technical quality of new grants	96*
c. Capability of research investigators	92
Q2. How adequate in general, is the initial review of traditional research project (R01) grant applications?	97*
Q4. How would you rate the:	
a. Value of site visits to the review process	90
b. Quality of site visits	91
d. Quality of discussion of applications during review sessions	91
Q5. How satisfied are you, on the average, with:	
b. The QUALIFICATIONS of scientific/technical members of the review and advisory groups?	95*
c. The PERFORMANCE of scientific/technical members of the review and advisory groups?	95*
Q6c. How would you describe the behavior of other team members during the review process?	92
Q7. How would you rate the qualifications and performance of NIH staff who administer the peer review system?	
a. Executive secretaries of initial review groups	94*
b. All other staff	91
Q8. Taking all significant factors into account, how would you characterize the NIH grant peer review system in toto?	96*
Q9. On the basis of YOUR OWN experience as a member of a review group, how would you rate the fairness and lack of bias of the NIH grant peer review system?	
a. In general	95*
b. With respect to performance of peer review group members	93*
c. With respect to NIH staff performance	94*
d. With respect to peer review system procedures	94*
Q10. Please indicate the extent of significant biases, if any, you have observed in the review of applications in recent years (percent responding none/insignificant)	
a. Age (anti-youth)	91*
c. Race (anti-minority)	98*
e. Sex (anti-female)	95*
B. 80 to 89 percent responding excellent/good (14 items)	
Q1. How adequate is the review currently performed for:	
d. Resources and environment required for research	81
f. Suitability of the requested period of budget support	83
Q4. How would you rate the:	
f. Effectiveness of the system of approval/disapproval/deferral	88
g. Effectiveness of the 1.0-5.0 priority system	82
i. Quality of summary statements (pink sheets)	86

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* At least half of those indicating an opinion selected "excellent" or "none".

TABLE 1. ASSESSMENTS OF THE CURRENT NIH RESEARCH GRANT REVIEW SYSTEM - CONT'D

QUESTIONS ON THE CURRENT SYSTEM (PART II OF QUESTIONNAIRE)	PERCENT
j. Procedures regarding possible conflict of interest	81
k. Review of competing renewal applications and their progress reports	89
l. Review of supplemental applications	85
m. Review of revised (amended) applications	87
Q5. How satisfied are you, on the average, with:	
a. The effectiveness with which the NIH grant peer review system uses your talents and expertise	88
f. NIH administrative policies and procedures for peer review	84
Q6a. How would you describe your overall working conditions during the review process?	87
Q10. Please indicate the extent of significant biases, if any, you have observed in the review applications in recent years (percent responding none/insignificant)	
g. Innovative ideas (anti)	84*
j. NIH staff interference	89*
C. 70 to 79 percent responding excellent/good (12 items)	
Q1. How adequate is the review currently performed for:	
b. Collaborative arrangements essential to research	79
e. Appropriateness of requested budget	78
Q3. How adequate, in general, is the initial review of program project and center grant applications?	78/1
Q4. How would you rate the:	
c. Time available for site visits	71
e. Time available for review	71
h. Effectiveness of the 100-500 priority score ranking system	77/1
Q5. How satisfied are you, on the average, with:	
d. The qualifications and performance of public members of advisory groups	70/2
e. The adequacy of the selection process for peer review group members	73/1
Q6. How would you describe your working conditions during the review process?	
b. In terms of the adequacy of the facilities provided	77
d. Enabling you to function at effective physical/mental levels (impact of fatigue)	71
Q10i. Please indicate the extent of cronyism, if any, you have observed in the review of applications in recent years (percent responding none/insignificant)	72
Q12c. Indicate your opinion of the present NIH requirement that the research grant applicant NOT be informed of individual reviewers' comments	71*
D. 50 to 69 percent responding excellent/good (3 items)	
Q1g. How adequate is the review currently performed for relevance of proposed research to NIH programs	67
Q12. Indicate your opinion of the present NIH requirement that research grant applicants NOT be informed of	
a. Overall Initial Review Group recommendations until after final Council/Board review	69
b. Initial Review Group priority scores	56

* At least half of those indicating an opinion selected "excellent" or "none".

/1 No opinion/no response rate was 17 to 25 percent.

/2 No opinion/no response rate was 42 percent.

. . . The adequacy of the review for program relevance, which is the primary responsibility of the National Advisory Councils/Boards, was assessed as excellent or good by 67 percent of the review group members, the second lowest rating for a specific feature of the current review system. DRG Study Section members, who are instructed not to concern themselves with this aspect of the review, were the least favorable while Institute IRG members, some of whom may consider this as part of their own function, were the most favorable (Table 9). Within all three types of review groups, members currently engaged in clinical activities were less satisfied than those not so engaged.

. . . The reviews for the appropriateness of the requested budget and for collaborative arrangements essential to research were perceived more favorably by members of both types of initial review groups, who are responsible for these functions, than by the members of the National Advisory Councils/Boards (Table 9).

. . . The time available for site visits was rated least favorably by the members of the Institute IRGs, the review group that is most concerned with such visits (Table 10). However, only 5 percent of this group rated the time available as either poor or very poor.

. . . The 100 to 500 priority score ranking system apparently posed a problem of understanding to members of both types of initial review groups as a high percentage did not respond to the question on the effectiveness of this system. However, about three-fourths of all those responding from each of the three review groups considered the system as either excellent or good (Table 10).

. . . Current restrictions on applicant notification had sizeable opposition. The present NIH requirement forbidding research grant applicants to be informed of their priority scores was perceived as a poor or very poor practice by almost one-third of all review group members. Approximately one-fifth of the members also objected to the other two current requirements listed--not informing the applicant of the overall IRG recommendation until after final Council/Board review and not making individual reviewers' comments available to applicants. However, a majority of all review group members regarded all three requirements as either excellent or good (Table 11).

. . . The time available for review appeared to be an area of some dissatisfaction. About 70 percent of all review group members rated the time available as either excellent or good. However, only 6 percent felt sufficiently dissatisfied to rate the time available for review as either poor or very poor. The greatest dissatisfaction was shown by the members of the National Advisory Councils/Boards (Table 12).

. . . Working conditions as measured by the facilities provided and the provisions made to enable the members to function at effective physical and mental levels were felt to be much less satisfactory by DRG Study Section members than by the members of the other two review groups. Members of the National Advisory Councils/Boards were very well satisfied (Table 12).

. . . The selection process for peer review group members was not heartily endorsed--less than three-fourths of all review members rated the adequacy of this process as excellent or good. In addition, the substantial no opinion/no response rates among all three types of review groups implies that many members may feel uninformed (Table 13).

. . . The public members' adequacy and performance was rated as excellent or good by slightly over two-thirds of the National Advisory Council/Board members. A very high proportion of initial review group members supplied no opinion as they probably had no basis for forming any opinions concerning the qualifications or performance of the public members who are not represented on their groups (Table 13). Among the National Advisory Council/Board members, opinions appeared sharply divided in such a way as to lead to the conclusion that the public members were rated less favorably by the scientific members than by themselves.

Changes in the Current System

The review group members were generally negative in their reactions to the suggested changes for "opening up" the present NIH research grant system. Only four of the 16 recent or potential changes listed in the questionnaire were perceived by a majority of members as probably having a "very favorable" or "favorable" impact on the quality and efficiency of the system (Table 2). In addition, one recently adopted change--opening review group sessions to the public when not reviewing applications or budgets--was considered by a majority as having either a favorable impact or "no impact."

Of the four suggestions for "opening up" the system which the majority of the survey respondents considered desirable, three involved increasing the access to the summary statements (pink sheets). Making these statements available upon request to review group members and, without the priority score, to principal investigators drew considerable support; less enthusiasm was shown toward making the summary statements available to principal investigators with the priority score. The fourth suggestion receiving majority approval dealt with making the critiques of the individual reviewers available to the principal investigators upon request (with the reviewers anonymous).

TABLE 2. ASSESSMENTS OF THE IMPACT OF RECENT AND POTENTIAL CHANGES

Grouped by the proportion of all review group members responding very favorable/favorable

Questions on the impact of recent and potential changes (Part III of questionnaire)		Percent responding	
		Very favorable/ favorable	No effect
A. More than 50 percent responding very favorable/favorable (4 items)			
Q6	Making summary statements (pink sheets) available upon request to:		
	a. Review group members	83	12
	b. The principal investigator, without the priority score	79	8
	c. The principal investigator, with the priority score	60	7
Q7a	Making the individual reviewers' critiques available to the principal investigator upon request, with the reviewers anonymous	53	6
B. 20 to 49 percent responding very favorable/favorable (3 items)			
*Q1	Release of new, funded grant applications to the public	24	25
*Q3	Opening the sessions of the Initial Review Groups and Advisory Councils/Boards to the public when not reviewing applications or budgets	34	37
Q6d	Making summary statements (pink sheets) available upon request to officials of the applicant institution	37	10
C. Under 20 percent responding very favorable/favorable (9 items)			
*Q2	Public release of all renewal/continuation applications (funded or not)	13	18
Q5	For those sessions which review grant applications		
	a. Opening Initial Review Group sessions to applicant investigators	7	4
	b. Opening IRG sessions to officials of applicant institutions	9	8
	c. Opening Initial Review Group sessions to the public	5	5
	d. Opening Advisory Council/Board Sessions to applicant investigators	8	7
	e. Opening Advisory Council/Board sessions to officials of applicant institutions	11	9
	f. Opening Advisory Council/Board sessions to the public	7	8
Q6e	Making summary statements (pink sheets) available upon request to the public	12	13
Q7b	Making the individual reviewers' critiques available to the principal investigator upon request, with the reviewers identified	5	2

* Practices already in effect at the time of the survey.

Even the three recently instituted changes toward "opening up" the system were expected to affect the NIH peer review system adversely. Approximately 70 percent of all review group members anticipated negative effects from the public release of renewal or continuation applications; one-half expected unfavorable effects from the public release of new, funded grant applications; and 30 percent regarded opening the sessions to the public when not reviewing either applications or budgets as having a very unfavorable or unfavorable impact.

Over 60 percent of the review group members were not aware of all three of the recently adopted changes toward "opening up" the NIH review system and a substantial 17 percent were not aware of any of them (Table 14). Such a lack of awareness on the part of the review group members raises the question of adequate communication. A mitigating factor may be the fact that many members are serving in the first year of their current appointment.

Another part of the questionnaire listed 20 suggested improvements and requested the review group members to rate these suggestions. The ratings designated by the review group members indicated a general satisfaction with the current system. /13 Of the 20 suggestions, only one--dealing with reducing delays--received strong support. Over three-fourths of all members endorsed a suggestion that a special study be made on how to shorten the time between the submission of an application and its subsequent funding or denial of funding. None of the other suggestions received approval from a majority of review group members (Table 3).

Seven of the 20 suggested improvements were considered as either excellent or very good by from 29 to 43 percent of the review group members. Of these seven suggestions, three dealt with reducing the workload of initial review group members. The method given the most support was to increase the number of review groups; over two-thirds rated this suggestion as fair or better. However, the other two methods suggested--reducing the maximum term of appointment to three years, and staff screening and rejection of inadequate applications--were rated poor or very poor by more than a majority.

Differences among the three types of review groups became apparent in the variations in their support of some of the suggested improvements. Although all three groups considered the special study on reducing delays as desirable, a majority of DRG Study Section members did not rate any of the other 19 suggestions as excellent or very good. However, a majority of Institute IRG members thought encouraging review group members to recommend site visits was an excellent or very good idea, as did a majority of National

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/13 An analysis of the Comments section of the questionnaire may indicate substantial support for improvements which were not listed in the questionnaire. Such an analysis will appear in Part II of the Report to the Survey Subcommittee.

TABLE 3. ASSESSMENTS OF SUGGESTED IMPROVEMENTS

Ranked by the proportion of all review group members responding excellent/very good

Questions on suggested improvements (Part IV of questionnaire)	Percent responding	
	Excellent/ very good	Fair
Q17. A special study on how to shorten the time between submission of an application and funding or denial of funding	77	14
Q2a. Reduce the workload of IRG members by increasing the number of review groups	43/1	26/1
Q9. Encourage review group members to recommend site visits	40/1	22/1
Q6. Provide a specific structured format for individual reviewers' reports	33	24
Q13. Permit an applicant to suggest reviewers in case of appeal only	31	26
Q8. Increase the number of site visits	30/1	24/1
Q2c. Reduce the workload of IRG members by reducing the maximum term of appointment to 3 years	29/1	18/1
Q2d. Reduce the workload of IRG members by staff screening and rejection of inadequate applications	29	13
Q5. Provide specific review format with weighted rating procedure for review criteria	27	22
Q11. Delay the appointment of a retiring member to another group for longer than the one-year moratorium now required between appointments	25/1	19/1
Q3. Increase the assigned reviewers for each proposal from to 3 in each IRG	25	20
Q2b. Reduce the workload of IRG members by increasing the number of members in each group	23	22
Q4. Curtail or omit discussion of those applications judged by assigned reviewers to be either outstanding or very poor	23	15
Q12. Permit an applicant to suggest reviewers	20	18
Q14. Include scientific/technical members employed by for-profit organizations on grant review groups	19	21
Q7. Decrease the number of site visits	1[illegible]/1	14/1
Q15. More frequent review group meetings	14	15
Q10. Discontinue site visits on research project (R01) applications	6	7
Q16. Less frequent review group meetings	3	12
Q1. Increase the workload of IRG members	2	5

/1 No opinion/no response rate was 15 to 27 percent.

Advisory Council/Board members. In addition, more than one-half of the National Advisory Council/Board members thought it would be an excellent or very good idea to have a specific structured format for individual reviewer's reports, to have a specific review format with weighted rating procedures for the review criteria, and to reduce the workload of initial review group members by increasing the number of review groups (Table 16).

More detailed discussions of specific aspects of the current NIH review system and of suggested changes or improvements are given in the last three sections of this report. In addition, certain significant aspects of the current NIH review system which have not been mentioned in this section because they did not fall into either the "most favored" or "least favored" groups are dealt with in some detail. These include all those aspects of the current system that were rated as excellent/good (or the equivalent) by from 80 to 89 percent of all review group members (Table 1).

MAINTENANCE AND IMPROVEMENT OF QUALITY OF REVIEW

PEER REVIEW GROUP MEMBERSHIP

SELECTION OF INITIAL REVIEW GROUP MEMBERS

It is clear, from the public hearings, letters, and discussions with other interested persons that: (1) the selection of initial review group (IRG) members is a sensitive issue of considerable interest; (2) there is a strong desire for more formal input from the scientific community and/or public regarding nominations for membership to IRGs; and (3) the method by which members are selected and the many considerations involved therein have neither been adequately described nor are generally understood.

I. BACKGROUND

The areas of biomedical science for which a particular initial group has review responsibility are briefly described in the HEW publication "NIH Public Advisory Groups, Authority, Structure, Function, Members". (1) A detailed and specific description of the review responsibility of each IRG in the Division of Research Grants (DRG) is further provided in the Referral Guide related to Study Sections (IRGs). (2) The latter is updated annually to reflect advances in the field and/or administrative changes in review responsibility of an IRG. In addition to providing technical merit review of applications, members also have the responsibility of surveying, as scientific leaders, the status and needs of research in their respective fields.

II. REVIEW OF CURRENT PROCEDURES, RESOURCES, AND SELECTION CONSIDERATIONS

A. Current Procedures

Formal nominations for membership to an initial review group originate with the Executive Secretary. One candidate is nominated for each position and the final selection is made by the Director, NIH, or his designee. The factors considered and resources available to an Executive Secretary in making these selections are discussed in subsequent sections.

A series of well defined procedures are followed, and review of all nominations is conducted at several levels within NIH and HEW before a nomination is approved and an invitation to IRG membership is extended by the Director or agency head.*

1. The Executive Secretary initiates a nomination by forwarding the "Request for Approval of Nominees for Public Advisory Committees" (Form HEW-532, Attachment 1) to the Committee Management Office(CMO) of the particular Bureau, Institute, or Division (BID). The information provided includes a description of the candidate's special expertise, type of qualifications needed for the position, proposed term of membership, and the nominee's curriculum vitae.

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*The Director, National Cancer Institute, has special separate statutory authority to establish advisory committees, 42 U.S.C. 282.

2. At the same time the Executive Secretary also forwards the list of nominees and the above information to the Chief of Extramural Programs (or other designated person) of the Institutes for which the IRG reviews substantial numbers of applications. The covering memorandum notifies the relevant Institutes of the proposed appointment and provides opportunity for informing the Executive Secretary of any serious questions or concerns regarding the nominations.

3. After the nomination(s) has been reviewed by the BID Director or his/her designee, the Committee Management Office (CMO) initiates an Availability Request Clearance which is forwarded, through the CMO of the Office of the Director, NIH, to the relevant office at HEW. There, information concerning previous membership on HEW committees and terms of office is provided and considered. The total time required for this action is six to eight weeks.

4. Prior to the issuance of an invitation, the Executive Secretary has a final opportunity to decide whether the specific nominee should be asked to serve on the IRG, since during the period between nomination and approval, membership requirements and/or conditions relating to the nominee's availability for service may have changed.

5. The BID Director or his/her designee issues the invitation to serve on the specific IRG for a specific term, in a letter which states the review and other functions of the IRG and describes the responsibilities incumbent upon such membership. Accompanying the letter of invitation are the required forms, including the Confidential Statement of Employment and Financial Interests (HEW-474, Appendix E-2) for determining potential conflict of interest.

6. When the letter of acceptance and the completed HEW-474 form are received, the latter is reviewed prior to final appointment.

7. Nominations for service as chairperson of an IRG require, in addition to the data supplied for regular membership, a memorandum describing the nominee's special qualifications for this position. Since prior service with the IRG is desirable, this selection is frequently made by the Executive Secretary from among the current members. In other cases, the nomination may involve reappointment of a former member of the IRG after a lapse of service and justification is required for this action.

B. Resources

The nomination and selection of members is a major professional responsibility of the Executive Secretary, involving long-range planning, suggestions, and information from many different sources. It is a matter of continuous research and concern. Numerous resources are available and are constantly drawn upon by the Executive Secretary in developing suitable nominations for membership:

1. The Executive Secretary's own knowledge of the discipline and of the scientists who are making significant research contributions to the field.

    a. Review of NIH applicant and grantee files and summary statements as well as curricula vita and publications of investigators.

    b. Reading of the major scientific journals and publications in the field.

    c. Attending relevant professional meetings. These provide a valuable additional way of keeping informed of the most significant new studies in the field and of identifying the investigators who are doing the research. Knowledge is thus gained of the interests and expertise of potential future IRG members. Such meetings also provide opportunity for consultation with eminent investigators who are not, or have not been, members of the IRG group.

2. Service of investigators as "special reviewers"; for example, (a) as ad hoc consultants at a regular IRG meeting when additional or special expertise is needed; (b) as members of a project site visit team; or (c) by providing written collateral opinions on request.

3. Solicitation of names of outstanding investigators in a given area from former and current IRG members and other leaders in the field.

4. Lists of women and minority scientists.

5. Consultation with scientific and professional staff of the various BIDs who have wide contacts with the scientists in a given field.

6. Attending, as observer, the review of applications by other agencies—especially those having review panels in related disciplines.

From a combination of such sources the Executive Secretary develops a large backlog of names of well-qualified scientists as potential IRG members. Nominees are selected from this list.

C. Nomination and Selection Considerations

The criteria, guidelines, and conditions for selection and appointment of members of NIH Initial Grant Review Groups have undergone changes and evolution since the peer review system was established. These are outlined in the memorandum to BID Directors dated 6/23/72 (Appendix D). More recently, proposed rules governing the composition of peer review groups (as published in the Federal Register, Vol. 41, #61, p. 12987) (Appendix F-2) are in the process of being codified.

In preparing a slate of nominees (usually three to five, one for each vacancy) as replacements and/or additions to the membership, a combination of specific criteria and conditions for appointment must be considered by the Executive Secretary relative to the present composition of the IRG. Some of the major considerations involved are listed below to emphasize their importance and interrelationships.

1. Areas and disciplines to be covered. Since the primary function of any IRG is to provide expert scientific merit review of the highest quality, the first and major consideration in selection of members is the particular area(s) of expertise needed. This relates not only to immediate or current needs but also to areas in which deficiencies will occur as other members complete their terms of service. In general, investigators with broad knowledge of the field, as well as excellent expertise in a specific subspecialty, are sought. The importance and the complexity of this function are formidable. Consideration of appropriate nominees for each opening requires not only the selection of people in specific disciplines but a search for and recognition of expertise in specific subdisciplinary areas. A balance of expertise in such areas in the entire committee is also required as is an understanding of the way in which the appointment of a specific individual would affect the spectrum of expertise--not only initially--but when other members retire. Specifically, this exercise requires this assessment over future years to assure the necessary balance and coverage for each new appointment proposed to the Initial Review Group. This function makes the greatest demands on the professionalism of the Executive Secretary and is perhaps the single most important determinant as to whether the IRG will operate efficiently with the appropriate balance and expertise.

2. Previous service, if any, on scientific merit review groups of NIH and/or other agencies. Before a nomination is sent forward it must be determined that the nominee is not currently a member of an HEW committee and has not served on such for at least one year prior to the expected date of appointment. It is the policy not to make reappointments to the same IRG group. Exceptions to these policies are rare and are made only in special cases. For example: (a) to appoint a chairperson of an IRG, since previous service on that review committee is valuable experience in undertaking this special responsibility; and (b) when the number of experts in a given field or subspecialty is so limited as to require reappointment. Other rare exceptions may involve dual appointments, when the nominee is, for example, serving on another NIH Advisory Committee such as the Board of Scientific Counselors of an Institute which reviews only intramural research activities.

3. Institutional Representation on Initial Review Groups. Individuals nominated for membership must be drawn from institutions not currently represented on the IRG. Two individuals from the same institution may not be appointed to a given IRG.

4. Geographic Distribution of Membership. An attempt is made to have representation from all areas of the U. S. and to maintain a balance with regard to geographic distribution in the nomination of new members. Again, this must take into account the location of current members and the time when each individual's appointment ends.

5. Minority Representation. Through the various resources mentioned above, there is a continual search both for ethnic group and women scientists who are experts in specific subspecialties that need to be represented. Equitable representation of such qualified individuals on the IRG must be an important consideration in selecting nominations; it is, again, also related to current composition of the IRG and the individual members' terms of service.

6. Term of Appointment. Although the appointments to an IRG are usually for a four-year term, members are sometimes nominated to serve for only two to three years for various reasons. In this regard, consideration is given to such matters as the nominee's other professional commitments, future plans for sabbatical leave, etc. A further factor is the number of members scheduled to complete their terms of service in a given year, to maintain a desirable balance between experienced and new members.

7. Personal Qualifications. Less tangible, but nevertheless essential additional considerations relate to judgment concerning: (a) the nominee's ability for functioning effectively and cooperatively with the group and with the Executive Secretary; and (b) the nominee's conscientiousness in fulfilling the obligations incumbent upon IRG membership, and for carrying out the objectives of the Peer Review System.

III. SUGGESTIONS FOR CHANGES IN THE SELECTION OF IRG MEMBERS

The Study Team's interactions with the scientific community and with the general public left little doubt that many individuals are concerned about how IRG members are--or appear to be--selected. Many of those who commented on the present grants peer review system expressed the belief that the pool of scientists from which NIH draws reviewers is unnecessarily and inappropriately narrow and that many qualified individuals consistently are overlooked. Others expressed uncertainty and uneasiness about the seemingly closed nature of the reviewer selection process and urged both more openness and broader participation by the scientific and lay communities. It is also apparent from the public hearings, the comments, and the letters received that most individuals do not know how IRG members are selected, nor are they aware of the care and wide variety of resources currently employed in making these selections. Thus the process described above seems to be one aspect of the NIH grants peer review system that is in need of clarification and could benefit from input from knowledgeable interested groups and/or individuals who are not now regularly consulted.

Given the widespread concern about so fundamental an element of the grants peer review system, the Study Team concluded that the NIH should make the details of its reviewer selection procedures more broadly known and, in addition, should provide a mechanism whereby individuals and organizations can suggest candidates for IRG membership.

The current practice of obtaining suggestions, for "replacements" or for future membership, from retiring or current members, has been challenged from various sources, on the basis that IRG members tend to perpetuate membership from their own institutions or from among their colleagues. The perception is that members choose their successors, or that, basically, they control who is invited to serve on IRGs. This misimpression can and should be corrected without delay, by: (1) much wider dissemination of information regarding the range of resources currently drawn upon by Executive Secretaries of IRGs; and (2) publication of the criteria and conditions for selection (as outlined in Appendix D).

Another suggestion has been made that current and retiring members should be specifically excluded from providing advice regarding replacements while they are still, officially, members of an IRG. Adoption of such a policy would, hopefully, aid in correcting the perception that a "buddy system" of selection exists. However, while this may be desirable for "cosmetic" reasons, it would weaken the continued effort to improve the quality of review and to obtain advice from highly knowledgeable sources. Those who are serving on a particular IRG are often in the best position of all potential consultants to know what the gaps in technical expertise are or are likely to be, and to provide suggestions as to the best qualified scientists to fill these needs. It would, therefore, be in the best interest of the maintenance of the quality of the Peer Review System to continue to seek suggestions from current, retiring, and former IRG members as well as from a wide variety of other sources.

It has been suggested that an IRG Executive Secretary provide a first and second nomination for each position to be filled. Presently, only one individual is nominated for each appointment to be made.

The possible advantages of having two nominees are: (a) if the first-choice nominee is unable to accept appointment there would be less delay in filling the position; (b) there could be more involvement of other interested parties such as staff of the various Bureaus, Institutes, and Divisions (BIDs) of NIH; and (c) the second nominee may help dispel the impression held by many that IRG and Council members personally select their own replacements and that IRGs and Councils are closed, select groups of self-perpetuating cronies representing and distributing research dollars only to the largest and most prestigious institutions.

Disadvantages are: (a) since the combination of conditions which must be met presently in the selection of only one suitable, available, and well-qualified expert per vacancy is a difficult and time-consuming undertaking, this would compound the problem; (b) since the scientific expertise, the location or university affiliation etc., of any one nominee is significantly related to other nominees in terms of scientific requirements and other conditions to be met, it cannot be considered in isolation from all other nominations or acceptances.

It is felt that the disadvantages outweigh the advantages of providing two nominations simultaneously for each position since this would add significantly to the background work of each Executive Secretary while giving little added flexibility. If the pool of known qualified investigators can be substantially increased by other methods, it appears that the current process of selection of one nominee for each vacancy should be continued.

Finally, the suggestion has been made that investigators may submit names of possible consultants who, they feel, are particularly knowledgeable in the technical aspects of the research proposed. This procedure is presently in effect but obviously it is not generally known. It is clear that a method must be devised to implement this procedure in a formal manner.

RECOMMENDATIONS:

1. THAT, IN ORDER TO MAKE THE REVIEWER SELECTION PROCESS BETTER AND MORE WIDELY UNDERSTOOD AND TO REGULARIZE THE WAYS IN WHICH THE SCIENTIFIC AND LAY COMMUNITIES CONTRIBUTE INFORMATION IN SUPPORT OF IT, THE NIH SHOULD PUBLISH PERIODICALLY (e.g., ANNUALLY) AN ANNOUNCEMENT WHICH CALLS ATTENTION TO THE UPCOMING VACANCIES ON IRGs ASSOCIATED WITH THE GRANTS PEER REVIEW SYSTEM AND WHICH INVITES SUGGESTIONS REGARDING CANDIDATES FOR SPECIFIC IRGs.

   The announcement should appear in the Federal Register and the NIH Guide to Grants and Contracts, and brief notices should be sent to scientific journals, such as Science, etc. Also, the announcement should be circulated among those individuals, institutions, scientific societies, and other organizations which request that their names be maintained on a mailing list for this purpose.

   The announcement should include the following items of information about:

   (a) the NIH grants peer review system:

   - o a brief statement of the role and importance of an IRG in the peer review process;
   - o a description of the nature and scope of an IRG member's duties, responsibilities, and workload;
   - o a description of the key steps in the reviewer selection process;

- o a listing of the professional characteristics that NIH looks for in selecting IRG members; and
- o a discussion of the other factors which are taken into consideration in selecting IRG members (e.g., geographical and institutional spread, representation of ethnic minorities and women, and other committee management limitations).

(b) each specific IRG:

- o its function;
- o the number of vacancies to be filled;
- o the areas of scientific and technical expertise to be represented by the new members.

Reference to the regularly published roster of NIH Public Advisory Groups should be included. (1)

It should be stated that potential respondents must document the qualifications of each individual suggested (attachment of curriculum vitae and bibliography, etc.) and specify the IRG(s) for which the individual is to be considered, if suggestions are to be considered. There also should be a clear statement that NIH, while willing to consider all submissions, reserves the right to make final selections without presenting public justifications or accounting specifically either to those who suggest candidates or to those who are suggested.

It is further recommended that responsibility for coordinating the preparation and distibution of the announcements and for providing suggested names to the appropriate IRG Executive Secretary should be centralized within the Office of the Director, NIH.

In addition, in order to assess its impact, the effects of this new procedure should be evaluated by carefully selected criteria within a given period of time (e.g., five years after implementation).

2. THAT, IN ORDER TO PROVIDE FOR ADDITIONAL ADVICE BEYOND THAT GIVEN BY INITIAL REVIEW GROUP MEMBERS, PARTICULARLY IN REGARD TO THOSE RESEARCH GRANT APPLICATIONS IN WHICH NEW SCIENTIFIC FIELDS ARE TO BE EXPLORED OR UNIQUE PROCEDURES ARE TO BE DEVELOPED, THE NIH SHOULD IMPLEMENT A FORMAL PROCEDURE WHEREBY AN APPLICANT MAY IDENTIFY THOSE PARTICULAR ASPECTS OF THE PROPOSED RESEARCH WHICH ARE CONSIDERED TO BE UNIQUE AND TO SUGGEST POSSIBLE CONSULTANTS WHO ARE CONSIDERED TO BE LEADERS IN AND CURRENTLY KNOWLEDGEABLE ABOUT HIS/HER AREA OF RESEARCH. HOWEVER, THE DECISION AS TO WHETHER TO SEEK ADVICE FROM THE SUGGESTED EXPERT(S) OR ANY OTHER EXPERT(S) MUST REMAIN THAT OF THE NIH.
(It is suggested that such proposals should be made in a separate letter which accompanies the grant application.)

3. THAT, THE CURRENT PRACTICE OF CONSULTATION WITH PRESENT, RETIRING, AND FORMER IRG MEMBERS CONCERNING POSSIBLE NEW MEMBERS SHOULD CONTINUE TO BE BUT ONE OF A SERIES OF STEPS BY WHICH ADVICE CONCERNING POTENTIAL IRG MEMBERS IS SOUGHT FROM MANY SOURCES.

4. THAT THE CURRENT PRACTICE OF PROVIDING ONLY ONE NOMINATION FOR EACH IRG VACANCY SHOULD BE RETAINED. FURTHERMORE, ADVICE REGARDING SUCH NOMINATIONS TO DRG INITIAL REVIEW GROUPS SHOULD BE SOUGHT FROM KNOWLEDGEABLE AND INTERESTED STAFFS OF THE VARIOUS BIDs RESPONSIBLE FOR THE ADMINISTRATION OF GRANTS IN THE PARTICULAR BIOMEDICAL SCIENTIFIC AREAS.

The above recommendations, when implemented, should lead to the selection of IRG members in the future by an open, objective process which assures that, as in the past, only qualified persons participate in peer review.

SELECTION OF INITIAL REVIEW GROUP MEMBERS

References

1. NIH Public Advisory Groups: Authority, Structure, Functions, Members. (Obtainable from Committee Management Office, Building 1, Room 303, National Institutes of Health, Bethesda, Maryland 20014. Published twice annually).

2. Referrral Guide in Relation to Study Sections. Division of Research Grants, National Institues of Health.

3. DHEW Scientific Peer Review of Grant Applications and Contract Projects. Fed. Reg. 41 (61): 12987 (1976).

Attachment 1.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
REQUEST FOR APPROVAL OF NOMINEES
FOR PUBLIC ADVISORY COMMITTEES
(See reverse for Instructions)

Date Prepared

☐ Principal
☐ Alternate

Name of Companion Nominee

Name of Nominee: *(last, first, middle, prof. degrees)*

Business Title:

Home Adress:

Business Address:

Date of Birth:

Place of Birth:

Agency:

Proposed Committee

☐ Initial Appointment
Proposed Term:
From:
To:

☐ Reappointment
Proposed Term:
From:
To:

Current Term:
From:
To:

Name of Retiring Member:

Termination Date:

Sources of Recommendations:

Name	Title	Date

Special Qualifications of Nominee *(briefly describe unique qualifications)*

Type Qualifications Needed for Committee Position

Previous Membership on DHEW Committees and Terms of Office

Program Director Recommendation/Approval

_______ BY: _______
Date

Agency Head Recommendation/Approval

_______ BY: _______
Date

Department Committee Management Office Concurrence

_______ BY: _______
Date

Assistant Secretary Recommendation/Approval

_______ BY: _______
Date

Assistant to the Secretary Recommendation

_______ BY: _______
Date

SECRETARY'S APPROVAL

_______ _______
Date Secretary

HEW-532 (Rev. 3/72)

SELECTION OF MEMBERS OF SPECIAL INITIAL REVIEW GROUPS (SIRGs)

Generally, research grant applications are reviewed by duly constituted Initial Review Groups (IRGs). However, certain conditions (described below) preclude the use of such IRGs for the review of special types of research grant applications. In such cases, Special Initial Review Groups (SIRGs) are organized, the membership of which reflects the review needs of a particular research grant application or group of applications.

I. CURRENT PRACTICE - SPECIAL INITIAL REVIEW GROUPS

The selection of special review group consultants is based on the guidelines set forth for IRGs (1) considering major factors such as scientific competence, and expertise in a particular scientific field as well as as standing in the scientific community and other factors such as conditions which could create conflict of interest situations, representation of women and minority groups, and the geographic distribution of consultants.

1. Conditions which govern the assignment of a research grant application to an SIRG include:

a. Submission by members of IRGs of applications for which there is no other IRG with the appropriate expertise to undertake review.

b. Submission of applications of such complexity that the scientific content overlaps the review area of two or more IRGs; e.g., Program Projects, Research Centers, Clinical Centers, or Biotechnology Resource applications.

c. Submission of applications in response to BID announcements of specialized program interests; e.g., Research Fellowship Awards, Request for Applications (RFAs), or International Fellowships.

d. Submission of applications for which it is determined that there are other special review requirements.

2. Process of selection of SIRG members

The SIRG Executive Secretary reviews the application(s) in question and develops a roster of potential reviewers after consultation with the Program Director of the BID to which the application has been assigned, making use of his/her previous experience and technical insight, and that of other Executive Secretaries having comparable review experience.

Other contributing sources frequently used to obtain consultants for an SIRG include: reviewers suggested by the Principal Investigator of the application to be reviewed, individuals identified in reference citations in the application, reviewers who have completed tenure on IRGs, as well as, on occasion, current IRG members who may have unique expertise. Whenever possible, highly qualified young investigators are invited to serve along with their more senior counterparts.

An SIRG generally consists of a minimum of 5 and a maximum of 12 depending upon the size and complexity of an application as well as the number of similar proposals to be reviewed. If a project site visit is required for the review of an application, the Principal Investigator receives a copy of the SIRG roster together with other pertinent details relevant to the pending site visit. The final SIRG roster may be modified upon the request of the Principal Investigator. However, assignment of an application to an SIRG does not always insure that a project site visit will be made.

Upon completion of a specific review assignment, the SIRG is dissolved.

II. IMPACT OF LEGISLATIVE PROPOSALS

A threshold question involves what constitutes a "committee." It is clear from the above that there is a recurring need to call together groups such as SIRGs, and, while the Federal Advisory Committee Act (FACA) does not distinguish between short-term and more permanent advisory groups, evidence that has been presented in this report would allow a strong argument to be made that "special" groups formed to review a single application or group of applications are not committees for the purposes of the FACA. However, pending legislation (Senate Bill No. S 2947) would amend the definition of "advisory committee" to encompass "*ad hoc*" groups thus making it impossible to set up SIRGs needed to provide for the important situations described above.

III. RECOMMENDATIONS AND DISCUSSION

1. THAT IT IS ESSENTIAL THAT NIH CONTINUE TO HAVE THE FLEXIBILITY AND OPPORTUNITY TO ESTABLISH SPECIAL INITIAL REVIEW GROUPS.

2. THAT NIH AND HEW SHOULD OPPOSE LEGISLATION REGARDING *AD HOC* GROUPS.

The review of applications assigned to SIRGs is complex. The workload is uneven and inconsistent. At times there may be a large number of applications to be reviewed; at other times there may be only a few; but in almost all cases the applications are complex and extraordinary skills are required in organizing appropriate SIRGs. Timing is important depending on availability of consultants willing to undertake review assignments which may require an absence of two to three days away from their own institutions, frequently on short advance notice. Furthermore, a mechanism for the proper review of applications from IRG members is necessary. It is therefore essential that NIH continue to have the flexibility and opportunity to establish SIRGs freed from the formality and delay involved in establishing IRGs.

3. THAT THE ROSTER OF CONSULTANTS TO BE INCLUDED ON A SPECIAL INITIAL REVIEW GROUP BE SUBMITTED TO ALL INVESTIGATORS.

Under the present system only those principal investigators for whose projects a project site visit is planned receive the roster of consultants prior to the site visit. This proposal would provide equity for all investigators whose applications are reviewed by SIRGs.

SELECTION OF MEMBERS OF SPECIAL INITIAL REVIEW GROUPS (SIRGs)

References

1. Handbook for Executive Secretaries. Division of Research Grants, National Institutes of Health; Fourth Edition. (1976).

NOMINATION, SELECTION, AND APPOINTMENT OF ADVISORY COUNCIL MEMBERS

Each of the awarding Bureaus, Institutes, and Divisions (BIDs), has a National Advisory Council or Board to offer advice and make recommendations on matters relating to the mission and goals of the Institute it serves. The Councils and Boards are specifically charged to review applications for grants-in-aid relating to research projects, grants and awards for research training and other activities as may be defined for accomplishing the mission of the awarding BID. The Council receives recommendations on applications for grants from initial review groups, which have been charged with making the scientific and technical merit review. The Councils or Boards advise on policy matters related to the development and management of grant programs and provide final review for scientific merit and program relevance of applications for grants-in-aid. They provide periodic review and evaluation of grant program accomplishments, help to identify and resolve problems in program development, and recommend guidance for the Institutes in the context of national health programs.

As established by law, each Council and Board is advisory to the Secretary, DHEW, through the Director, NIH, and the Director of the awarding BID.* For the most part, the membership of each Council or Board consists of the Secretary, DHEW, or his designee, plus leaders in the fundamental sciences, medical sciences, education and public affairs as may be approved by the Secretary.

I. PROCEDURES AND GUIDELINES FOR SELECTION OF COUNCIL OR BOARD MEMBERS

The Public Health Service (PHS) Act (1) directs the Secretary, DHEW, to appoint members to NIH Advisory Councils in accordance with the requirements set forth by each of the sections of the Act which apply to the particular Council.** These requirements, in general, are designed to provide authorities knowledgeable in the programmatic areas within the Institute's mission, familiar with the NIH procedures, aware of the roles of diverse institutions in biomedical research, and mindful of the health needs of the American people. To provide this range of expertise, each Council consists of both scientists and public members. Ex officio members from other Federal agencies are appointed as required by law.

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*With the exception of the National Cancer Advisory Board which is advisory directly to the Director, NCI.

**Members of the Board of Regents of the National Library of Medicine and of the National Cancer Advisory Board are appointed by the President.

A. Criteria for Selection

1. Scientific Members

Individuals selected as scientific members are chosen from among those recognized as outstanding leaders in their fields and considered to have a broad interest in and understanding of the relationship of biomedical science to societal needs. It is expected that the Council members will have recognized achievement in a relevant field, other scientific accomplishments, and honors. The assessment of appropriate abilities and accomplishments is based primarily on the general recognition by peers in the biomedical areas as a broadly based expert in the current and past development and status of a particular field of research. In addition to superior accomplishment, the characteristics of mature judgment, balanced perspective, and objectivity are essential. Candidates must have demonstrated the capability of working effectively in a group context as committee members. Those who accept appointment are expected to accept responsibility for all work assignments.

2. Public Members

Individuals selected as public members should have a demonstrated interest and background history relevant to the program of the Institute. These individuals should have knowledge concerning the needs and aspirations of society in the areas of the mission of the Institute.

3. General Criteria and Policy for Selection of Council Members*

a. Within a given Council, representation of needed scientific disciplines or medical research specialties must permit the attainment and maintenance of a proper balance to cover the range of the mission and goals of the Institute.

b. Whenever possible, selection of candidates should reflect an equitable representation of the geographic regions of the U. S. These considerations, however, must remain subsidiary to and should not take precedence over the appointment of individuals of the highest qualifications.

c. No two members of a Council should be appointed from the same institution or organization.

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*These general criteria and policies apply only to advisory bodies appointed by officials within DHEW. Even where the appointing official is the Secretary or other DHEW official, exceptions to these criteria and policies may be permitted.

d. No new member should be appointed to the same or any other Council within a year after termination of a prior appointment. No member may serve concurrently on more than one DHEW advisory group.

e. Within the criteria, guidelines, and conditions noted above, NIH practice is to utilize the widest available pool of qualified candidates for advisory service, including equitable representation of minorities, women, and youth. Considering all these factors, primary consideration for Council nominations should be given to scientific leaders in their specific fields of competence and lay representatives of demonstrated interest and background relevant to the program of the Institute to which they have been nominated as Council members.

4. Procedures for Nominating Candidates for Advisory Councils

The general procedure is for NIH to nominate one primary and one alternate for each vacancy on an Advisory Council. (Each professional or scientific vacancy on a Council is usually limited to a specific medical or scientific need; see A-3a.) The Office of the Secretary, DHEW, may request additional nominations and/or make nominations itself. Once the Secretary, DHEW, selects a candidate to fill a Council vacancy, he sends a letter of invitation. The PHS Act directs the Secretary to appoint members to Advisory Councils in accordance with the requirements set forth by each of the sections of the Act which apply to the particular Council. A recent and most welcome addition is that all appointments to advisory committees to assist in implementing the Publc Health Service Act are required to be made without regard to political affiliation.*

II. DEFICIENCES AND/OR PROBLEMS ENCOUNTERED IN CURRENT SELECTION PRACTICES

Appointments to Councils are for overlapping terms of four years. Vacancies occur automatically at the expiration date. Unless filled in a timely fashion, a vacuum is created and the Council will function at less than optimum efficiency. Maintaining a Council at full strength is essential if it is to function effectively. At present, the NIH has no knowledge of or control over the timing of appointments of new Council members. Both delayed appointments and unfilled vacancies continue to threaten the efficient operation of the Councils. For example, there are 153 authorized Council positions. One-quarter of these terminate annually as individual terms expire. Forty-four appointments are needed to fill the vacancies for the calendar year, 1976. As of November 1, 1976, the 44 positions still remain vacant.

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*Section 1001, Public Law 94-278, Health Research and Health Service Amendments of 1976.

The PHS Act authorizes the Council to advise on policy matters related to the development and management of grant programs. It also authorizes the Council to provide a second review for scientific merit and program relevance of applications for grants-in-aid. In general, no grant can be awarded unless recommended for approval by the awarding unit's advisory council or board. Serious operational problems can and do occur when substitutes for NIH nominated candidates are made without NIH knowledge and concurrence. In such instances, the discrete balance of scientific specialities necessary to cover the range of areas of expertise required by the Institute's programs can be destroyed with the resultant effect that the Advisory Council may have no representation for one or more research areas (and other areas may have duplicate representation). Unless there is adequate and appropriate representation for each of the major areas of concern to each Institute, the Council will lack the ability to carry out its statutory responsibility with maximum effectiveness.

III. RECOMMENDATIONS AND DISCUSSION

1. THAT NIH SHOULD SEEK TO HAVE THE AUTHORITY FOR SELECTION AND APPOINTMENT OF MEMBERS OF ADVISORY COUNCILS/BOARDS DELEGATED TO THE ASSISTANT SECRETARY FOR HEALTH, DHEW.

Maintaining a Council at full strength is essential for the Council to effectively meet its responsibilities as a reviewing body for applications and advising the Institute on program priorities and balance. At present the NIH has no knowledge of or control over the selection or appointment of new Council members. Unfilled vacancies, delayed appointments, and the appointment of individuals lacking in the required expertise continue to threaten the effective operation of Advisory Councils. It is essential that someone knowledgeable of the needs of the Institutes, and the roles of and requirements for Advisory Council members, has responsibility for assuring that the total selection and appointment process proceeds in an effective and timely manner. The Assistant Secretary for Health, the highest department health official, has the background and scientific knowledge to carry out these requirements.

2. THAT THE PROCEDURE FOR NOMINATING AND SELECTING COUNCIL MEMBERS BE MORE OPEN. SCHEDULED COUNCIL VACANCIES SHOULD BE ANNOUNCED AND PUBLISHED EARLY IN THE FISCAL YEAR. THE ANNOUNCEMENT SHOULD SPECIFY THE COUNCIL INVOLVED, THE CRITERIA FOR THE SELECTION OF COUNCIL MEMBERS, THEIR DUTIES, AND TERMS OF APPOINTMENT. THE NAMES OF INDIVIDUALS SELECTED SHOULD BE PUBLISHED TOGETHER WITH THEIR QUALIFICATIONS.

The Grants Peer Review Study Team, in assessing the perceptions of the scientific and informed lay community as to the duties of and criteria for selection of Council members, became aware that there was misinformation and, in many cases, lack of knowledge as to the duties and functions of the Advisory Councils as well as the criteria and methods for the selection of Council members. Accordingly, the GPRST urges that there be wide dissemination of information as to the duties and functions of the Advisory Councils and the methods by which members are selected.

3. THAT, WHEN A SELECTION HAS BEEN MADE FOR A COUNCIL VACANCY(IES) OTHER THAN FROM NOMINATIONS SUBMITTED BY THE DIRECTOR, NIH, THE APPOINTMENT SHOULD NOT BE MADE FINAL UNTIL THE DIRECTOR, NIH, HAS HAD THE OPPORTUNITY TO COMMENT ON THE SELECTION.

Through its experience, the NIH has acquired considerable knowledge of the appropriateness of many individuals to serve on a Council and an appreciation of their effectiveness. By implementing the above procedure, the risk of appointing inappropriate or potentially ineffective members would be avoided.

NOMINATION, SELECTION, AND APPOINTMENT OF ADVISORY COUNCIL MEMBERS

References

1. Public Health Service (PHS) Act, [42 U.S.C. 241].

CONSIDERATIONS IN REGARD TO CONFLICT OF INTEREST

THE UTILIZATION IN NIH COMMITTEE MANAGEMENT OF THE FORM HEW 474 (CONFIDENTIAL STATEMENT OF EMPLOYMENT AND FINANCIAL INTERESTS)

In accordance with Civil Service Commission and HEW requirements, NIH periodically secures from each member of its advisory committees a Form HEW 474, regarding the member's employment and relevant financial interests.

I. Background:

Generally speaking, the Federal conflict-of-interest statutes make it a crime for a special Government employee (such as an advisory committee member who is not otherwise employed by the Government), except in the discharge of his/her official duties, to represent anyone else in a particular matter in which the United States is a party or has a direct and substantial interest and (1) in which he/she has at any time participated personally and substantially in the course of his/her Government employment, or (2) which is pending before the Government agency he/she serves. There is also a criminal sanction against an employee participating as part of his/her official duties in a particular matter in which, to his/her knowledge, the employee's spouse, minor child, partner, or a profit or nonprofit enterprise with which he/she is connected, has a financial interest. 1/ (Appendix E-1)

As written, the conflict-of-interest statutes simply describe the prohibited activities and the penalties involved, but do not specifically require agencies to take steps to prevent potential violations thereof. Nevertheless, although individuals are, in theory, charged with notice of the criminal laws, it is often not readily apparent that the laws apply in certain contexts. Hence, agencies do undertake to assist employees in avoiding violations of these laws. This is reflected, for example, in the HEW Document, Standards of Conduct, which discusses conflict of interest in detail, sets forth a procedure for obtaining advice on such matters, and even has a separate subpart addressed specifically to special Government employees. Another example is the procedure outlined elsewhere in this report by which NIH deals with applications from advisory committee members' own institutions or from the members themselves.

1/ It should be emphasized that this is only a general description of these statutes. For a more detailed discussion, see the HEW Standards of Conduct, 45 C.F.R. Part 73.

II. The Form HEW 474

Only the individual member normally has the basic information about his/her activities which is necessary to avoid all but the most obvious conflict-of-interest situations. A major purpose of the Form HEW 474 (Appendix E-2) is to direct the member's attention to the subject of conflict of interest and to require him/her to consider his/her own activities in light thereof. A second goal of the form is to aid agencies in identifying situations in which potential conflicts may exist.

Agencies are required to secure this form from special Government employees by Executive Order 11222 which reads in pertinent part as follows:

> "Sec. 306. Each agency shall, at the time of employment of a consultant, advisor, or other special Government employee require him to supply it with a statement of all other employment. The statement shall list the names of all corporations, companies, firms, State or local governmental organizations, research organizations and educational or other institutions in which he is serving as employee, officer, member, owner, director, trustee, adviser, or consultant. In addition, it shall list such other financial information as the appointing department or agency shall decide is relevant in the light of the duties the appointee is to perform. The appointee may, but need not, be required to reveal precise amounts of investments. The statement shall be kept current throughout the period during which the employee is on the Government rolls."

This provision has been implemented by Civil Service Commission and HEW regulations. 2/ (5 C.F.R. §735.401 et seq.; 45 C.F.R. §73.735-1201 et seq.) Among other things, these regulations prescribe the contents of the Form HEW 474; require that the form be reviewed by a high level agency official; and specify that the form be maintained in the appropriate personnel office but separate from the official personnel folder. The regulations permit agencies to make the completed forms ". . . available only as specifically authorized by the head of the operating agency . . . for good cause shown . . .," but this would not prevent full-time Federal employees (such as Executive Secretaries) from looking at the forms in connection with their official duties.

In order to implement the aforequoted portion of the Executive Order at its level, NIH has published Manual Issuances 2300-735-1 and 2300-735-2, dealing with conflicts of interest on the part of special Government employees. The former (Appendix E-3) is a one-page document which simply directs consultants and advisors to submit Forms HEW 474

2/ The HEW regulations are commonly referred to as the HEW Standards of Conduct.

and to update them on a yearly basis and requires NIH staff to issue a copy of the Standards of Conduct to all newly appointed or reappointed consultants and advisors, together with a memorandum from the Secretary, HEW, alerting HEW personnel to become familiar with the contents thereof.

As had already been indicated, the Standards of Conduct regulations require that each Form HEW 474 be reviewed by a high level official " . . . to determine whether conflicts of interest or apparent conflicts might arise from the activities reported thereon." The Standards also contain sections relating to such specific matters as professional and consultative services, writing and editing, publishing, teaching, and holding office in professional societies or State or local government.

NIH Manual Issuance 2300-735-2 is entitled "Conflict of Interest Policy for Committee Members." (Appendix E-4) It sets forth guidelines for the selection and appointment of members to avoid certain types of conflicts, but places on the committee member ". . . the primary responsibility for evaluating his financial interests or those of his family, that relate directly or indirectly to his duties." It assigns to the BID Directors responsibility for determining who shall review information on the Form HEW 474 and who shall have access to such information. The only specific responsibility given to the Executive Secretary is to remind committee members periodically about ". . . NIH and other pertinent policy regarding avoidance of conflict-of-interest situations."

Since the Executive Secretary plays such a central role in the actual operation of committees, the Director, DRG, has established a policy (Appendix E-5) for the DRG study sections which provides as follows:

> "1. Each Executive Secretary, prior to a regular study section session, shall review in [Mrs. Pollak's] office the forms 474 on file for that study section. Such notes as necessary may be made.
>
> 2. Study section members who identify themselves on Form 474 as affiliated with organizations shall not participate in the discussion or vote on an application from any organization so listed. In other words, the present policy of nonparticipation on applications from major employers shall be in effect for these organizations.
>
> 3. At the close of each study section meeting, each member must certify that he/she was absent during the discussion of matters from any and all institution or institutional systems with which he/she is affiliated. The exact wording of the certification to be signed will be developed by the Chief of the Scientific Review Branch and approved by me. As you will note in the report, this is current practice for council members.

4. Each Executive Secretary must prepare a list of applications for which he/she excused certain study section members from review. This list should give the name of each excused member under the pertinent application number. This list is to be attached to the original copy of the formal minutes and retained in the study section's official files. The duplicated copies of the minutes should contain a statement to this effect. The standard statement is to be developed by the Chief, Scientific Review Branch, for all to use."

The Grants Peer Review Study Team recognizes that it is essentially impossible for an agency such as NIH to take cognizance of sufficient information about advisory committee members to note and avoid all potential conflicts of interest. Hence, NIH justifiably places primary responsibility for avoiding these conflicts on the members themselves. Nevertheless, NIH also has a duty to see that members are informed about conflict-of-interest considerations and to take reasonable steps to help in the identification and avoidance of potential conflicts. The Form HEW 474 serves the multiple purpose of bringing the conflict-of-interest requirements to members' attention, causing them to think about these requirements in relation to their own situations, and of providing NIH with added information for use in identifying possible problems in this area.

Although the Form HEW 474 contains useful instructions, it is the Study Team's view that they are too general to fully meet NIH's needs. As a result, some IRG members interpret the instructions too narrowly and fail to list relevant information.

The Study Team endorses the approach being taken by DRG of requiring Executive Secretaries to become familiar with information on their members' Form HEW 474s. The Executive Secretary is the NIH staff person who is most knowledgeable about the backgrounds of the members and the business of the particular committee, and therefore is in the best position to anticipate and prevent potential conflicts.

III. Recommendations

Regarding Form 474:

1. THAT NIH DEVELOP DETAILED SUPPLEMENTAL INSTRUCTIONS TO BE SENT TO MEMBERS ALONG WITH THE FORM HEW 474, EMPHASIZING THAT EMPLOYMENT INCLUDES, FOR EXAMPLE, FOREIGN EMPLOYMENT, SUMMER AND PART-TIME EMPLOYMENT, MEMBERSHIP ON ADVISORY BOARDS OF ORGANIZATIONS, AND CONSULTANT APPOINTMENTS; AND THAT RELEVANT FINANCIAL INTERESTS INCLUDE SUCH THINGS AS ROYALTY AGREEMENTS WITH OR STOCK OWNERSHIP IN DOMESTIC OR FOREIGN BIOMEDICAL RESEARCH ORGANIZATIONS, COMPANIES ENGAGED PRIMARILY IN PROVIDING SERVICE TO SUCH ORGANIZATIONS, PHARMACEUTICAL COMPANIES, AND OTHER COMPANIES INVOLVED IN DRUG RESEARCH.

2. THAT NIH ADOPT A PROCEDURE UNDER WHICH FORM HEW 474 IS RETURNED TO A MEMBER AS INCOMPLETE, WHERE SUCH MEMBER MAKES NO ENTRY IN A SECTION OF THE FORM BUT DOES NOT WRITE "NONE" OR SOME EQUIVALENT IN THE SECTION.

3. THAT THE EXECUTIVE SECRETARIES OF IRGs BE GIVEN ACCESS TO THE FORMS HEW 474 OF MEMBERS, AS NEEDED.

4. THAT REVIEW OF FORMS HEW 474, AT LEAST ANNUALLY, BY EACH EXECUTIVE SECRETARY BE MANDATED THROUGHOUT NIH.

5. THAT ALL EXECUTIVE SECRETARIES BE REQUIRED PERIODICALLY TO ATTEND TRAINING SESSIONS ON EVALUATION OF CONFLICT-OF-INTEREST SITUATIONS.

IV. Invitations to Members

Under current practice, once an individual is selected to serve on an advisory committee, if the appointing official is at NIH, the Form HEW 474 will be sent out along with the invitation to membership. Where a higher level official makes the appointment, the Form HEW 474 often is not mailed to the selected individual until after the invitation is made.

While the format of the invitation letters may vary, in general, they do not make it explicit that the invitation is a contingent one, and that final appointment depends on, among other things, review of the completed Form HEW 474 to determine whether, in light of conflict-of-interest restrictions, the individual will be able to participate sufficiently in the activities of the committee to make a meaningful contribution to the work of the committee. Moreover, in most instances, once the invitation is made, the individual will not receive another formal communication indicating that his/her appointment is final. It is not surprising, therefore, that individuals would normally assume that the initial invitation is tantamount to a final appointment.

This assumption is reinforced by the fact that NIH has sometimes included an invitee's name on membership lists released to the news media and other members of the public, after the invitee has agreed to serve, but before the individual's Form HEW 474 has been reviewed from a conflict-of-interest standpoint.

In the opinion of the Study Team, this approach downplays the importance of the review of the Form HEW 474 to an unwarranted extent, so that once an individual receives an initial invitation and accepts, it will be difficult for the appointing official finally to reject the individual on conflict-of-interest grounds, as well as embarrassing for the individual if such a rejection should occur.

V. RECOMMENDATIONS

A. Regarding Invitations to Members:

1. THAT ALL INITIAL INVITATIONS TO SERVE ON ADVISORY COMMITTEES MAKE IT EXPLICIT THAT FINAL APPOINTMENT IS CONTINGENT UPON REVIEW OF THE COMPLETED FORM HEW 474 FOR CONFLICTS OF INTEREST, OR POTENTIAL CONFLICTS OF INTEREST, AND THAT THE NEW MEMBER BE FORMALLY NOTIFIED OF THE APPOINTMENT AFTER THE APPOINTMENT PROCESS (INCLUDING REVIEW OF THE FORM HEW 474) HAS BEEN COMPLETED.

2. THAT THE NAMES OF NEW MEMBERS OF ADVISORY COMMITTEES NOT BE RELEASED TO THE NEWS MEDIA OR OTHER MEMBERS OF THE PUBLIC UNTIL SUCH TIME AS FINAL APPOINTMENT HAS OCCURRED AFTER COMPLETION OF THE FORMS HEW 474.

APPOINTMENT OF EMPLOYEES OF FOR-PROFIT ORGANIZATIONS TO NIH INITIAL REVIEW GROUPS

Under current NIH policy, full-time employees of "for-profit" organizations and institutions may not be appointed to National Institutes of Health Initial Review Groups (IRGs). At the request of the Office of the Director, the Grants Peer Review Study Team was asked to review this policy and to formulate a recommendation either as to its retention or for change.

I. BACKGROUND*

The present NIH policy which does not permit the appointment of individuals employed by profit-making organizations to serve on initial review groups had its origin in two Presidential documents, issued in February 1962 and signed by President John F. Kennedy. The first, dated February 9, 1962, was relevant strictly to "Preventing Conflicts of Interest on the Part of Advisors and Consultants to the Government."(1) The second, dated February 26, 1962, was issued as Executive Order #11007, "Prescribing Regulations for the Formation and Use of Advisory Committees."(2) Both of these documents now have been superseded by more recent issuances, the first in Regulations, Title 45, Part 73, Standards of Conduct(3), promulgated by HEW, and the second by the Federal Advisory Committee Act of 1972 (P.L. 92-463)(4).

The Presidential memorandum of February 9, 1962, set down specific rules for the appointment of consultants and advisors so that a determination could be made as to the status of each individual in regard to conflict of interest. The necessity for such rules was precipitated by an opinion rendered by the then Attorney General concluding that the conflict of interest statutes of the United States Code (18 U.S.C. 281) applied not only to consultants and advisors when they were actually employed by the Government, but were also applicable throughout the entire period of such appointments when employment by the Government was for forty percent or more of the total appointment period. Section 281, 18 U.S.C., in general, precludes a government employee from acting in matters that come before government departments or agencies on behalf of a nongovernment employer from which he or she receives compensation. The effect of this regulation was to require NIH to make a determination about each consultant as to whether or not his non-Federal employment status created a conflict of interest situation while such an individual was acting as a consultant to the Government. The present HEW Form 474 is used for this purpose (Appendix E-2).

Based on this Presidential memorandum, instructions were given to NIH to terminate all committee memberships as of July 30, 1962, and to reappoint only those individuals about whom it could be determined that there was no conflict of interest. It was found that there was considerable difficulty in making such a determination in regard to consultants who were employees of profit-making organizations, and thus a decision was made not to reappoint such persons.

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*A file on all the background and historical documents is available in the Grants Peer Review Study Team office.

The pertinent portions of Executive Order #11007 stated that no advisory committee might be formed unless it was specifically authorized by law or specifically determined as a matter of formal record by the head of a department or agency to be in the public interest. Further, any advisory committee, the duration of which was not fixed by law, was to terminate not later than two years from its date of formation unless the department or agency head specifically determined that its continued existence was in the public interest. However, Section 9 of this Executive Order stated that these requirements did not apply "to any advisory committee composed wholly of representatives of state or local agencies or charitable, religious, educational, civic, social welfare, or other similar nonprofit organizaton." This reinforced the NIH decision to exclude employees from "for-profit" organizations from serving on advisory committees (except on those established by specific legislation, e.g., advisory councils).

As stated previously, Executive Order #11007 was superseded by the Federal Advisory Committee Act of 1972 (P.L. 92-463). However, the section of the Executive Order quoted above was not included as part of the new legislation; and thus all committees established and utilized by NIH, regardless of their composition, are now subject to the requirements of the Federal Advisory Committee Act. Current Federal regulations (Title 45, Part 73), established under this act, are equally applicable to all consultants regardless of the profit status of their non-Federal employers.

Thus there must be adequate review of the Conflict of Interest Statements (HEW Form 474) filed by all consultants; and there no longer seems to be any barrier to the appointment of employees of profit-making organizations to serve on any NIH committee, provided it can be determined that a conflict of interest does not exist when performing the required duties. Indeed, the requirements in this regard must be no different for individuals who are employees of nonprofit organizations.

II. CONSIDERATIONS BY THE GRANTS PEER REVIEW STUDY TEAM

The Study Team recognizes that competent scientists are employed by both nonprofit and "for-profit" organizations. Furthermore, it is evident, upon review of the Conflict of Interest Statements (HEW Form 474) currently on file, that many present appointees to NIH IRGs are consultants to industrial firms and are not considered to have a conflict of interest as far as service on an NIH IRG is concerned. It would thus appear that both consultants to and employees of industry should be considered equally satisfactory for service on NIH initial review groups.

The Study Team also is of the opinion that, in some areas of scientific research, persons with certain talents, skills, and expertise are to be found in the industrial sector who do not exist in adequate numbers in the nonprofit sector. The use of such experts, when needed in the review of grant applications, should not be denied to NIH. Furthermore, in recent years, NIH has had to draw on an ever-increasing number of individuals for consultant services in order to meet certain other requirements; thus, the pool of scientifically knowledgeable individuals has to be increased. The untapped resource of employees of the industrial sector would reinforce the pool of available experts upon which NIH can draw for consultant services.

Based on the above considerations and the background information, the Study Team makes the following recommendations:

III. RECOMMENDATIONS

THAT EMPLOYEES OF "FOR-PROFIT" ORGANIZATIONS BE ELIGIBLE FOR MEMBERSHIP ON ALL INITIAL REVIEW GROUPS CONSIDERING GRANT APPLICATIONS (INCLUDING NATIONAL RESEARCH SERVICE AWARD APPLICATIONS), AND THAT THE SELECTION OF THESE INDIVIDUALS BE BASED ON THE SCIENTIFIC PROFICIENCY NECESSARY TO FILL THE VARIOUS NEEDS OF SPECIFIC COMMITTEES. THE BASIS FOR SELECTION OF SUCH SCIENTISTS SHALL BE THE SAME AS FOR THOSE EMPLOYED BY "NON PROFIT" ORGANIZAITONS.

THAT THE CONFLICT OF INTEREST STATEMENTS (HEW FORM 474) SUBMITTED BY EMPLOYEES OF PROFIT-MAKING ORGANIZATIONS NOMINATED AS CONSULTANTS MUST BE REVIEWED BY THE AGENCY HEAD, WHO MUST BE SATISFIED THAT EACH NOMINEE CAN SERVE ON THE SPECIFIC COMMITTEE FOR WHICH SUCH PERSON HAS BEEN PROPOSED WITHOUT BEING IN VIOLATION OF THE CONFLICT OF INTEREST STATUTES.

IV. CRITERIA FOR SELECTION OF IRG MEMBERS FROM "FOR-PROFIT" ORGANIZATIONS

The Study Team suggests that the criteria stated below be considered as part of the above recommendation:

1. General

THE CRITERIA FOR SELECTION OF IRG MEMBERS FROM "FOR-PROFIT" ORGANIZATIONS SHOULD BE NO DIFFERENT THAN THOSE FOR SELECTION OF PERSONS FROM "NONPROFIT ORGANIZATIONS."

2. Specific

a. Recognized achievement in a relevant field.

For scientific merit review of research grant applications, an individual serving on an NIH initial review group should have particular competence as an independent investigator in the needed scientific discipline or research specialty. Demonstration of such competence is based on the quality

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of research accomplished, productivity in the form of research reports published in scientific journals, and other significant scientific activities, accomplishments, and honors.

Assessment is based primarily on the general recognition by a scientist's peers of the individual's abilities and accomplishments as a careful, critical, original, and deliberate investigator, and as a broadly based expert in the past development and current advancement of a particular field of research. Usually the M.D., Ph.D., or equivalent advanced degree is required; however, a doctoral degree is not required in those circumstances where an individual's experience clearly indicates outstanding competence.

Furthermore, a reviewer of applications for National Research Service Awards must have had substantial experience in graduate research training, with an active interest in the methods and planning of research training in his or her discipline, field, or specialty, and a record of accomplishment in such training.

b. Mature judgment and objectivity as a scientist.

The characteristics of mature judgment, balanced perspective and objectivity are essential to the merit review process.

c. Ability and willingness to serve.

(a) A candidate must have demonstrated the capability of working effectively in a group context.

(b) A candidate who accepts appointment to an NIH advisory group is expected to accept responsibility for all work assignments and must protect the confidentiality of applications and reviewer opinions.

d. Conflict of interest.

The Conflict of Interest Statement (HEW Form 474) submitted by a nominee must be reviewed by the agency head who must be satisfied that the individual can perform as a special government employee without being in violation of conflict of interest statutes.

V. Implementation of the Study Team Recommendation

In order to implement the above recommendation, guidelines for the selection of all consultants to NIH initial review groups, but particularly those in regard to persons from "for-profit" organizations, should be reviewed periodically; and, where necessary, modifications should be made so that the criteria for selection of individuals are such as to retain the quality of consultant advice that NIH expects from its advisors.

APPOINTMENT OF EMPLOYEES OF FOR-PROFIT ORGANIZATIONS TO NIH INITIAL REVIEW GROUPS

References

1. Kennedy, John F., Preventing Conflicts of Interest on the Part of Advisors and Consultants to the Government; February 9, 1962.

2. Kennedy, John F., Prescribing Regulations for the Formation and Use of Advisory Committees. Executive Order #11007, February 26, 1962.

3. Regulations, Form HEW-539, Title 45, Part 73, Standards of Conduct, September, 1970.

4. Public Law 92-463, Federal Advisory Committee Act, October 6, 1972.

LEGAL CONSIDERATIONS REGARDING GRANTS PEER REVIEW

LEGAL CONSIDERATIONS REGARDING GRANTS PEER REVIEW

In recent years, the public, the Congress, the Executive Branch, and the courts have become increasingly attentive to and supportive of greater public accountability and openness in Government. Recent legislation, court cases, and proposed legislative action in this area have important implications for the operation and continued effectiveness of the NIH peer review system. At the same time, the Congress and the President's Biomedical Research Panel have strongly endorsed this system, praising its fairness, objectivity, and high quality. The strengths of the system must be preserved while it is kept publicly accountable.

I. Background

A. Peer Review Legislation

In discussing the peer review system in a 1973 report, the Senate Committee on Labor and Public Welfare endorsed the comment that: "The peer review system [at NIH] has given us the best science through a federal agency with the least political interference of any governmental process ever developed. It is truly one of the great achievements of American government. . . " Under this system, each application to NIH for a research grant is initially reviewed for scientific merit by a group of experts in relevant biomedical fields. The recommendation of the group is then considered by an appropriate National Advisory Council or Board, made up of both scientists and lay persons, which makes a final recommendation to NIH on the application based not only on scientific merit but also program priority.

Each of the NIH Bureaus, Institutes, and Divisions (BIDs) awarding grants has a National Advisory Council or Board whose members generally are leaders in science, education, or public affairs. Section 301 of the Public Health Service (PHS) Act [42 U.S.C. 241], the basic authority under which NIH research project grants are made, provides that no grant may be awarded for a research project unless it is first "recommended" for funding by the appropriate National Advisory Council or Board. 1/ A similar requirement exists in Section 472 of the PHS Act [42 U.S.C. 2891-1], relating to National Research Service Awards to individuals for research and research training. In addition, a number of the Councils are assigned responsibilities for advising their respective BIDs on other specific program activities (Title IV, PHS Act, 42. U.S.C. 281 *et seq.*).

1/ By statute, the National Cancer Institute and the National Heart, Lung, and Blood Institute may award research project grants, without Council or Board review and recommendation, where the awards are for $35.000 or less in direct costs.

In general, the National Advisory Councils were established by law at the same time as the BIDs to which they give advice and have been responsible, by statute, for advising on grant applications since their establishment. On the other hand, prior to the passage of the National Cancer Act of 1971 [Public Law 92-218], there was no actual statutory requirement that research grant applications be reviewed as well by scientific peer review groups, e.g., NIH Initial Review Groups (IRGs). However, the National Cancer Act of 1971 amended the PHS Act to require the Director, NCI, to ". . . provide for proper scientific review of all research grants . . . over which he has authority (1) by utilizing to the maximum extent possible, appropriate peer review groups established within the National Institutes of Health . . . and (2) when appropriate, by establishing . . . other formal peer review groups as may be required." [42 U.S.C. 2863.]

The National Cancer Act Amendments of 1972 [Public Law 93-352] in effect extended this requirement of scientific peer review to all " . . . applications . . . for grants under . . . [the PHS] Act for biomedical and behavioral research . . . " (Appendix F-1). It further required that such review be conducted " . . . to the extent practical . . .. in a manner consistent with the system. . . " being utilized on the date the amendments became effective and that not more than one-quarter of the members of any peer review group may be officers or employees of the United States, presumably apart from their service as members of the group. [42 U.S.C. 289l-4.]

On March 29, 1976, a notice of proposed rulemaking (Appendix F-2) was published in the Federal Register setting forth proposed regulations to implement the foregoing provisions (41 F.R. 12986). In general, these regulations codify the pre-existing NIH system for scientific peer review of grants.

The Health Research and Health Services Amendments of 1976 [Public Law 94-278] include a section which states in pertinent part that "All appointments to advisory committees established to assist in implementing the Public Health Service Act . . . shall be made without regard to political affiliation."

B. Conflict of Interest

With regard to conflict of interest, the aforesaid regulations would essentially codify prior NIH practice which requires that members of peer review groups in no way participate in deliberations or actions concerning applications from their own institutions and that they leave the room before any such discussions. Where one of the members of the group, which would normally review a particular application, is actually named in the application as the principal investigator or a principal staff member, the application is assigned to another peer review group with the requisite competence, or if none exists, it is assigned to a special (ad hoc) initial review group, no more than 50 percent of the membership of which may be from the groups of which the investigator or staffer is a member.

These actions have been considered sufficient by the Department of Health, Education, and Welfare to avoid any violation of the conflict-of-interest statutes, and they were endorsed by the Congressional committees which considered the proposals concerning peer review that were finally enacted as part of Public Law 93-352.

The foregoing conflict-of-interest requirements were recently upheld by the United States District Court for the Northern District of California, in an opinion dated February 10, 1976, stating that these requirements " . . . designed to avoid conflicts of interest in the grant application review process [are] adequate and reasonable . . . " (Grassetti v. Weinberger, et al., C.A. No. C-75-1198-SC.) (Appendix F-3).

II. The "Sunshine" Laws

The so-called "Sunshine" Laws affecting NIH are the Freedom of Information Act (FOIA), the Privacy Act, the Federal Advisory Committee Act, and the Government in the Sunshine Act.

The general thrust of the Freedom of Information Act is to make available to the public upon request any and all of the records of Federal agencies. The Privacy Act seeks to protect the individual from the Government's collection and use of data concerning the individual without his or her knowledge or consent and to provide the individual access to those Government records which include information pertaining to him or her. The Federal Advisory Committee Act seeks to assure public knowledge about meetings of Governmental advisory groups as well as public access to these meetings. The Government in the Sunshine Act sets forth the circumstances in which NIH may close advisory group meetings to the public.

The specific provisions of the above Acts impact on the peer review system because of their applicability to all significant documents connected with the process and to the operation of committees charged with peer review. The current and potential effects of these laws and proposed amendments to them are examined below in terms of changes in the peer review system, the quality of the peer review process, and related consequences.

A. Freedom of Information Act

1. Description of the Law.

This Act (FOIA), originally adopted in 1967 [Public Law 90-23] and amended in 1974 [Public Law 93-502], requires agencies to make available to the public for inspection and copying, any requested Government records. (Appendix F-4). However, subject to provisions of the Privacy Act, discussed below, requests for records may be denied if those sought fall within any one of nine specified "exemptions" set forth in the FOIA. Only the following three exemptions presently bear on the peer review system:

> "(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;
>
> "(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;
>
> "(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."

2. The Washington Research Project Case.

Until recently, all requests under the FOIA for grant applications (funded or unfunded), interim progress reports, summary statements of IRG reviews, and site visit reports were denied, based primarily on exemption 4. To the extent that these materials contained discussions of the qualifications of individuals, such discussions were considered to be protected as well by exemption 6. Additionally, since the summary statements and site visit reports reflected the deliberations and opinions of the members of advisory groups and site visitors, these items were also viewed as being within exemption 5.

In Washington Research Project, Inc., v. Weinberger, et al., a public interest group challenged the Department's denial of the plaintiff's request for the foregoing categories of documents, relating to specific funded initial applications and funded and unfunded continuation, supplemental, and renewal applications. The United States District Court for the District of Columbia ruled that essentially all the materials in question were available under the FOIA. (366 F. Supp. 929.) On appeal, the Court of Appeals for the District of Columbia agreed with the lower court that the protocols and progress reports at issue were not covered by exemption 4, but held that the portions of summary statements and site visit reports reflecting the deliberations of members of advisory groups and site visitors were exempt from mandatory disclosure under exemption 5. (504 F. 2d 238.) (Appendix F-5). In light of the appeals court decision, which is now final, current Department practice is to release, upon request, funded initial grant applications and continuation, supplemental, and renewal applications (whether or not funded), as well as interim progress reports, except insofar as disclosure of any particular items would adversely affect patent or other valuable rights. In so doing, any confidential financial information concerning the applicant or grantee will be deleted. As in the past, requests for summary statements and site visit reports will largely be denied.

3. Availablity of applications.

It is almost impossible in the short run to measure the impact of the FOIA and the Washington Research Project decision on the peer review process. It has been suggested, however, that scientists may be less willing to include new ideas in their applications if they may be available to the public, thereby diminishing the usefulness of such an application in determining which projects to fund. If applicants do react in this way, reviewers will have to depend more heavily on site visits, the general reputation of investigators, and subjective evaluations. This will tend to work against the new investigator and the novel idea.

In its Report to the President and Congress, dated April 30, 1976, the President's Biomedical Research Panel, established pursuant to Public Law 93-352, concluded that this was a real concern and recommended that:

> "The Public Health Service Act . . . should be amended to provide a statutory exemption from disclosure [under] . . . the Freedom of Information Act for research designs and protocols contained in grant applications . . . until the grant . . . funds have been received by the grantee institution . . . Unfunded grant applications . . . should remain confidential."

In a second Report (June 30, 1976) mandated under the Health Research and Health Services Amendments of 1976 [Public Law 94-278] and entitled "Disclosure of Research Information," the Panel reaffirmed its prior conclusion, expressing the conviction that unless the intellectual property rights of investigators are adequately protected, ". . . the federal biomedical and behavioral research effort and its impact on the health of the nation—is likely to be impaired . . . " The Panel went on to say that disclosure of information from research protocols did not appear to contribute to the improvement of peer review. Rather, the Panel expressed the belief that such disclosure ". . . could impair the ability of the [peer review] system to ensure high-quality federally funded research." It pointed out that ". . . the credibility of peer review would certainly be undermined if it were compromised by the submission of derivative proposals and applications and if the judgments by peer review groups were based on incomplete information."

The findings set forth in the Survey of the NIH Research Grant Peer Review System, reported elsewhere herein, tend to support the conclusions of the Panel, for only one-eighth of the advisory committee members surveyed favored the public release of all renewal and continuation applications whether or not they had been funded. (Supplement A, p. 55)

RECOMMENDATION:

THAT THE PHS ACT BE AMENDED TO PROVIDE STATUTORY EXEMPTION FROM THE REQUIREMENTS OF THE FREEDOM OF INFORMATION ACT FOR DISCLOSURE OF RESEARCH DESIGNS AND PROTOCOLS PRESENTED IN GRANT APPLICATIONS.

(This is, in essence, an endorsement of the recommendation of the President's Biomedical Research Panel.)

B. Federal Advisory Committee Act (FACA)

1. Description of the Law.

This Act (FACA), approved on October 6, 1972 [Public Law 94-463], states that "No advisory committee shall meet or take any action until an advisory committee charter has been filed with . . . the head of the agency to whom . . . [the] advisory committee reports . . . " (Appendix F-6) The term "advisory committee" is defined (subject to certain exemptions not here relevant) to include " . . . any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof . . . except that such term excludes . . . any committee which is composed wholly of full-time officers or employees of the Federal Government." All meetings of advisory committees must be advertised in the Federal Register, and (subject to the discussion which follows) all portions must be open to the public. Effective until March 1977, there is an exception to the open meeting requirement, where " . . . the head of the agency . . . determines [the meeting] is concerned with matters listed in Section 552(b) of Title 5, United States Code." Section 552 is commonly referred to as the "Freedom of Information Act," and paragraph 552(b) thereof sets forth the exemptions from mandatory disclosure which were discussed above in connection with the FOIA. Thus, until March 1977, a meeting may, in effect, be closed insofar as the subject matter being discussed, if reduced to writing, would be exempt from mandatory disclsoure under the FOIA.

The Government in the Sunshine Act [Public Law 94-409] recently amended the FACA (effective in March 1977) to permit an exception for a portion of a meeting only where " . . . the head of the agency . . . determines that such portion . . . may be closed in accordance with Subsection (c) of Section 552(b) of Title 5, United States Code." Section 552(b) was added to the United States Code by Public Law 94-409 and deals primarily with the decision-making processes of agencies headed by collegial bodies composed of two or more persons appointed by the President with the advice and consent of the Senate. Subsection (c) of Section 552(b) contains a list of exemptions from the requirement that these bodies hold their meetings in open session. The subsection provides in pertinent part that:

> "Except in a case where the agency finds that the public interest requires otherwise . . . [portions of an agency meeting may be closed] where the agency properly determines that such portion or portions of its meeting . . . is likely to—
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> * * * * *
>
> "(4) disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential;
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> * * * * *
>
> "(6) disclose information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy;
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> * * * * *
>
> "(9) disclose information the premature disclosure of which which would—
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> * * * * *
>
> "(B) in the case of any agency, be likely to significantly frustrate implementation of a proposed agency action, except that subparagraph (B) shall not apply in any instance where the agency has already disclosed to the public the content or nature of its proposed action, or where the agency is required by law to make such disclosure on its own initiative prior to taking final agency action on such proposal;"

While exemptions 4 and 6 in subsection (c) of Section 552(b) are similar to those in the FOIA, the new law does not contain any exact counterpart to FOIA exemption 5. On the other hand, it does contain a new exemption 9B which could be applicable to meetings of peer review groups.

In considering whether to use an exemption to close a portion of a meeting under subsection (c), an agency head must decide if it is "likely" that exempt matters or information will come up, not simply that there is a possibility of it occurring.

2. What constitutes a "committee"?

A threshold question concerns what constitutes a "committee" for purposes of the FACA. In order to comply with conflict-of-interest requirements or to review certain types of applications, it is regularly necessary to call together what are commonly referred to as "special," or "*ad hoc*," initial review groups to consider one, or a small number of applications, usually on a one-time basis. The FACA itself does not distinguish between short-term and more permanent advisory groups nor does it make any specific mention of "special," or "*ad hoc*," groups. In *Food Chemical News, Inc., v. Davis*, 378 F. Supp. 1048 (D.D.C. 1974), a United States District Court held that two separate informal meetings between Treasury Department officials and consumer and industry representatives, at which the officials secured advice relative to regulations on labeling of distilled spirits, were covered by the FACA. On the other hand, in *Nader v. Baroody*, 396 F. Supp. 1231 (D.D.C. 1975), another judge in the same court ruled that bi-weekly White House meetings with selected groups from the private sector were not within FACA's ambit. In the latter case, the court cited with apparent approval the following criteria for determining whether a gathering is an "advisory committee" under FACA:

> "(a) Fixed membership, usually selected by a Federal official or determined on the basis of Federal Law;
>
> "(b) Established by a Federal official or on the basis of Federal law; or, if not federally established, the initiative for its use as an advisory body for the Federal Government came from a Federal official rather than from a private group;
>
> "(c) A defined purpose of providing advice regarding a particular subject or particular subjects;
>
> "(d) An organization structure (e.g., officers) and staff;
>
> "(e) Regular or periodic meetings."

Under these criteria, a strong argument could be made that "special," or "*ad hoc*," groups formed to review a single application or groups of applications are not committees for purposes of FACA.

On February 6, 1976, Senate Bill No. S. 2947 was introduced which, among other things, would amend the definition of "advisory committee" to encompass "*ad hoc*" groups. (Appendix F-7). In light of the realities regarding time needed to charter committees, passage of this amendment would probably make it impossible to utilize "special" or "*ad hoc*" groups in the conflict-of-interest situations discussed above, or to meet short term workload increases in specialized areas.

RECOMMENDATION:

THAT NIH AND HEW PRESENT SPECIFIC WRITTEN OPPOSITION TO ANY LEGISLATIVE PROPOSAL EXTENDING THE FEDERAL ADVISORY COMMITTEE ACT TO "AD HOC" OR SPECIAL REVIEW GROUPS. BASED ON THE NEED TO PREVENT CONFLICTS OF INTEREST IN THE PEER REVIEW OF GRANT APPLICATIONS AND THE NEED TO RETAIN FLEXIBILITY IN MEETING SHORT TIME WORKLOAD INCREASES IN SPECIALIZED AREAS.

3. Closing meetings.

When the FACA was first passed, portions of meetings devoted to review of grant applications were closed primarily under FOIA exemptions 4 and 6, on the basis that discussions were likely to cover matters affecting patent and other valuable rights, and that negative comments about the qualifications and ideas of investigators and others could institute a clearly unwarranted invasion of their personal privacy. While the deliberations of the peer review groups would seem also to be covered by exemption 5, the Department severely limited use of this exemption, to avoid excessive closure of meetings. In the Washington Research Project case, however, the Court of Appeals indicated that the deliberations of the peer review groups, as set forth in the summary statements, deserved exemption 5 protection. As a result, the Department agreed to a relaxation of its restrictions on using exemption 5 to close meetings. Since then, exemptions 4, 5, and 6 have all been cited as bases for closure to review grant applications.

On April 6, 1976, the United States Court of Appeals for the District of Columbia, in Aviation Consumer Action Project, et al., v. Washburn, et al., ruled that exemption 5 was available as a basis for closing of meetings, thereby overturning, in effect, several lower court opinions to the contrary. This decision provided added support for use of that exemption in connection with review of grant applications (Appendix F-8).

As has already been indicated, Public Law 94-409 carried forward exemptions 4 and 6, as grounds for closing meetings, essentially without change. Thus, where applicable, these exemptions can continue to be cited to support the closure of meetings. On the other hand, in its Report on Public Law 94-409, the Conference Committee indicated that one of the purposes of the amendment to FACA was to overrule the Washburn decision. At the same time the conferees stated that:

> "The conferees, however, are concerned about the possible effect of this amendment upon the peer review and clinical trial preliminary data review systems of the National Institutes of Health. The conferees thus wish to state

> as clearly as possible that personal data, such as individual medical information, is especially sensitive and should be given appropriate protection to prevent clearly unwarranted invasions of individual privacy. While the conferees are sympathetic to the concerns expressed by NIH regarding its committees' funding recommendations and analysis of preliminary data, the conferees are equally sympathetic to concerns expressed by citizens' groups that important fiscal and health-related information not be unnecessarily withheld from the public.
>
> "With these competing interests in mind, the conferees have secured assurances that the appropriate House and Senate committees will review the unique problems of NIH under the new standards. Indeed, it is noted that the subcommittee on Reports, Accounting and Management of the Senate Government Operations Committee has already held three days of hearings on this matter and plans to continue with further inquiry at an early date."

In its Report of April 30, 1976, the President's Biomedical Research Panel noted the important concern expressed in evidence to the Panel over the possibility that meetings of peer review groups might be opened to the general public. The Panel noted that:

> "Aside from the obvious likelihood of a decrease in the candor of the reviewers and the lack of any indication of how the members would be protected professionally and financially from vengeful acts and charges of libel or bribery, open meetings would have at least two other objectionable features. The first would be the reluctance of many qualified scientists to participate as members of Study Sections and Review Committees. The second concern relates to the untenable discrimination between investigators from two classes of applicant organizations: those able to send observers because of geographic proximity to the review meeting, local representation, or financial means, and those unable to take advantage of the open sessions."

The Panel therefore recommended that the Public Health Service Act be amended ". . . to provide statutory assurance that the initial review for scientific and technical merit ("peer review") remain totally confidential."

This is in accord with the overwhelming sentiment of members of advisory groups surveyed by the NIH Grants Peer Review Study Team. Only five percent were in favor of opening IRG sessions to the public, and just seven percent supported such opening simply to the investigator. Figures were only slightly higher for Advisory Board and Council sessions concerned with grant application review. (Supplement A, p. 56).

C. Privacy Act (PA)

1. Description of the Law.

This Act, approved on December 31, 1974, and effective in pertinent part on September 27, 1975, [Public Law 93-579], regulates the collection, maintenance, and use of information about individuals in agency systems of records. (Appendix F-9) The term "system of records" is defined to cover " . . . a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some . . . other identifying particular assigned to the individual." The Privacy Act also requires agencies to establish procedures under which such individuals are given access to and an opportunity to seek correction or amendment of this information.

2. Availability of summary statements and reviewers' opinions to the principal investigator.

On March 8, 1976, the Associate Director for Extramural Research and Training, NIH, published an Instruction and Information (I&I) Memorandum, OERT 76-1, concerned primarily with the Privacy Act, but dealing as well with the FOIA. (Appendix F-10). The I&I memorandum indicates that: "All NIH official files for grants . . . " constitute a system of records under the Privacy Act. In discussing release of information under the Privacy Act to such individuals as principal investigators, program directors, and fellowship awardees, the I&I memorandum further provides that:

> "When the subject individual makes a request for information from a record pertaining to him/her, all fact and opinion pertaining to the subject individual of the record should be released to him/her under the PA. (The names of the outside reviewers, i.e., persons who are not members of standing or ad hoc committees and who, at the request of NIH staff, submit opinions in writing, are not to be listed on the summary statement, but are listed elsewhere in the official record). In addition, all factual information from the summary statement is available to the subject individual, e.g., name of investigator, title of project, description of project, budget of project."

The I&I memorandum goes on to state that the priority score will not be released and the NIH " . . . will release verbatim only what is required under both PA and FOIA." 3/

3/ The priority score is not considered by NIH to be "about" the investigator and is therefore not subject to the Privacy Act. Also, NIH takes the position that release of the priority score is not required under FOIA because it falls within exemption 5.

With respect to site visit reports and opinions of outside reviewers (persons whose opinions have been obtained but who are not members of the review group), the I&I memorandum states:

> "NIH has generally taken salient information from the site visit reports and outside opinions for incorporaton into the summary statement. After information is incorporated into the summary statement, the site visit report and outside opinions are not retained.
>
> "If a specific request [by the principal investigator] is made for access to these reports while still in our [NIH's] possession, appropriate information . . . from them must be provided to the requester.
>
> "The name of an outside reviewer is not deleted from documents representing his/her opinions, e.g., mail reviews, site visit notes submitted by individual site visitors. When Executive Secretaries prepare site visit reports and summary statements, they will not ordinarily associate individual opinions with reviewers names, however."

The survey of advisory group members conducted by the Study Team showed that 79 percent of those responding favored the rule set forth in the I&I memorandum of releasing the summary statement to the principal investigator without the priority score. (Supplement A, Page 56.) However, a substantial majority, 60 percent, believed that the priority score should also be released, with an additional seven percent indicating that release would have no effect on the quality or efficiency of the peer review system. A majority, 53 percent, supported release of individual reviewers' opinions if the reviewers remained anonymous, with an added six percent in the "no effect" category, but only five percent would agree to such disclosures with the reviewers identified.

In the judgment of the Study Team, these results reflect a recognition on the part of those surveyed that the principal investigator has a right to the complete and detailed record of review group action on his or her research proposal. This is evidenced by the respondents' overwhelming support for release of the summary statement, with or without the priority score, to the investigator. On the other hand, if an individual reviewer is identified to the investigator as having expressed a particular opinion on the proposal, whether or not adopted by the review group as a whole, this is likely to affect the candor of such opinions in the future. As a result, those surveyed did not favor release of such opinions unless the reviewers' anonymity was protected.

The Study Team believes that, inasmuch as the review group members themselves do not believe that summary statements should be kept from the principal investigator, there is little justification for not so releasing them, whether or not required to do so under the Privacy Act. Also, for reasons outlined elsewhere in this report, the Study Team feels that the priority score should not be deleted.

With respect to individual reviewers' opinions, the Study Team recognizes that, in accordance with the Privacy Act, these must normally be released to the principal investigator. In view of the survey results indicating that more than half of those responding were in favor of such disclosure, provided that the reviewers' identity is not revealed, the Study Team sees no substantial reason for objecting thereto. At the same time, the Study Team urges that steps be taken to establish an adequate legal basis for protecting the reviewer's anonymity either through reinterpretation of existing law, if reasonably possible, or enactment of new legislation, under circumstances in which release of reviewers' opinions is required under the Privacy Act.

RECOMMENDATIONS:

THAT THE SUMMARY STATEMENTS BE MADE AVAILABLE UPON REQUEST TO THE PRINCIPAL INVESTIGATORS, INCLUDING THE PRIORITY SCORES.

THAT IN RELEASING REVIEWERS' OPINIONS UNDER THE PRIVACY ACT, AN ADEQUATE LEGAL BASIS BE ESTABLISHED FOR PROTECTING THE REVIEWERS' ANONYMITY EITHER THROUGH REINTERPRETATION OF EXISTING LAW, IF REASONABLY POSSIBLE, OR ENACTMENT OF NEW LEGISLATION.

D. Effect of Sunshine Laws on Scientific Progress

It is clearly not possible at the present time to make an assessment of the effect of the recent Sunshine Laws on the progress of biomedical research in this country. However, it seems possible that, if investigators conclude that it is contrary to their best interests to include details of new experimental and theoretical approaches in research proposals, the vagueness of such applications will be interpreted as weakness in the scientific undertaking. This could result in the stifling of innovative research and decreased support of new investigators who have little or no background or history of research activity upon which reviewers may judge merit. If so, the very life blood of scientific progress, namely innovation, and youth may be lost.

Thus, it would appear essential that the impact of this new legislation be evaluated periodically so as to assess these factors.

The Study Team believes that the concerns expressed by the President's Biomedical Research Panel are well founded. If NIH were required to open meetings, it is likely that reviewers would have reservations about providing candid, negative criticisms of research proposals. This would undoubtedly result in ambiguous and superficial evaluations, reducing the quality of the judgments by the review groups and thus the quality of NIH granting operations, which allocated about $1.3 billion in fiscal year 1975. Also, some individuals might even be unwilling to serve on review groups for fear of harassment.

RECOMMENDATION:

THAT THOSE PORTIONS OF THE MEETINGS OF ADVISORY GROUPS WHICH INVOLVE THE REVIEW OF GRANT APPLICATIONS CONTINUE TO BE CLOSED TO THE PUBLIC (INCLUDING THOSE SUBMITTING APPLICATIONS), EITHER UNDER CURRENT EXEMPTIONS TO THE OPEN-MEETING REQUIREMENT OR THROUGH A STATUTORY AMENDMENT

4. Review Group Membership

Another change in the FACA proposed in Senate Bill No. S. 2947 (referred to above) would be to require that one-third of the members of each Federal advisory group " . . . be drawn from citizens in private life who shall represent the interests of the Public . . . " (Appendix F-7). If such a provision is interpreted to require the appointment of individuals without scientific expertise to IRGs, this would destroy the fundamental principle of the dual peer review system, namely that the quality of research proposals is best assessed by experts in particular fields, who are scientific or technical "peers" of the applicants. This is accomplished at the first stage of review by the IRGs. Broader public input is then obtained at the second level of the dual review system when the proposals are considered by the National Advisory Councils and Boards made up of leaders, not only in scientific fields, but also in education and public affairs.

RECOMMENDATION:

THAT, NOTWITHSTANDING PROPOSALS WHICH WOULD REQUIRE PUBLIC REPRESENTATION ON ALL COMMITTEES, THE CURRENT SYSTEM OF DUAL REVIEW BE PRESERVED, WITH GRANT APPLICATIONS BEING REVIEWED FIRST BY INITIAL REVIEW GROUPS CONSISTING SOLELY OF SCIENTIFIC AND TECHNICAL EXPERTS AND THEN BY NATIONAL ADVISORY COUNCILS AND BOARDS WHICH INCLUDE REPRESENTATIVES OF THE PUBLIC.

RECOMMENDATION:

THAT THE NIH AND HEW ESTABLISH A MECHANISM FOR SPECIAL, PERIODIC ASSESSMENT OF THE IMPACT OF THIS NEW LEGISLATION ON THE QUALITY OF GRANT APPLICATIONS AND ON THE QUALITY OF PEER REVIEW OF SUCH APPLICATIONS AND THAT SUCH ASSESSMENT BE REPORTED TO THE LEGISLATIVE AND EXECUTIVE BRANCHES OF THE GOVERNMENT.

IMPACT OF REVIEW WORKLOAD ON QUALITY OF INITIAL MERIT REVIEW

IMPACT OF REVIEW WORKLOAD ON QUALITY OF INITIAL MERIT REVIEW

Over the past several years the workloads of many of the Initial Review Groups (Study Sections) have increased to levels which can only be defined as excessive. During a period in which there were reductions in the federal workforce, including the NIH peer review workforce, and new controls were placed on the formation and use of advisory groups, the peer review workload increased in size and complexity. The demands being placed upon already overburdened peer review group members and NIH executive secretaries will, unless corrective actions are taken very soon, result in a lower quality of peer assessments and recommendations.

I. BACKGROUND

Members of NIH grant review groups have expressed a decided reluctance to assume further peer review responsibilities: 97% of study section members, 86% of members of other NIH initial review groups, and 90% of responding members of Advisory Councils and Boards rated the suggestion that initial review group members' workload be increased as poor or very poor, in the survey conducted by the Study Team (Supplement A). In addition, there are currently problems in regard to (1) the adequacy of summary statements, (2) loss of continuity and quality in communications within the NIH on peer review issues, and (3) inadequate flow of information between NIH staff and applicant-investigators. The administration of the NIH peer review process, including quality control, is becoming more difficult, as the workload increases quantitatively and also becomes more complex.

THE STUDY TEAM IS CONVINCED THAT WORKLOAD PROBLEMS MUST BE RESOLVED NOW, TO PREVENT DETERIORATION OF THE SYSTEM. IN PRESENTING RECOMMENDATIONS WHICH ADDRESS THIS PROBLEM, THE STUDY TEAM EMPHASIZES THE IMPORTANCE OF MAINTAINING THE INTEGRITY OF THE PEER REVIEW SYSTEM AND ITS ABILITY TO FUNCTION EFFECTIVELY.

The international respect accorded the NIH and the major role of the NIH in biomedical research over the years, have been achieved, in large part, through the accomplishments of NIH grantees, whose research was supported by about 60% of the total NIH budget in fiscal year 1975. Since the NIH peer review system is the primary quality control mechanism for the allocation of grant funds, the quality and consistency of the grant peer review process must receive full respect and protection from any forces which threaten its integrity.

The Study Team is also sensitive to the fact the "peers" must be considered a resource to be protected. The NIH should not abuse or alienate this resource, which has performed so well over the years.

II. CURRENT STATUS OF THE NIH GRANTS PEER REVIEW SYSTEM, IN TERMS OF IRG WORKLOAD

The workload problem is the first issue to be raised whenever NIH staff members discuss the peer review system. DRG has sent forward to OD, NIH, several reports of studies by executive secretaries, suggesting alternate ways to reduce Study Section workloads. Participants in workshops sponsored by the NIH Executive Secretaries Review Activities Committee (ESRAC), reported in recent recomendations to the Deputy Director, NIH,(1) calling attention to the seriousness of this problem.

The Study Team is concerned that review overload either already has or will have adverse effects on:

- The quality of peer review recommendations.
- The ability of NIH to recruit and retain outstanding experts to serve on peer review groups.
- The willingness of peer group members to take on more work.
- The openness of peer review groups to unique or "unorthodox" research ideas.
- The ability of NIH to recruit and retain individuals of high competence to serve as peer review group executive secretaries.
- The quality of documentation of peer review recommendations and technical critiques in site visit reports and summary statements.
- The ability of NIH staff responsible for peer review to perform to their best capability.
- The quality and extent of the assistance that executive secretaries can provide applicants prior to review by identifying additional information needed.
- The quality and depth of information provided to grant applicants on the substance of the peer review recommendations and specific critiques.
- The timely review of grant applications.

The increased workload of grant review groups is most readily demonstrated in terms of the number of applications per review group per review session, shown in Figures 1, 2, and 3. This increase has been accompanied by a decline in the review workforce. The number of grant applications reviewed by individual DRG Study Sections in May and June 1976 for the September/October 1976 Advisory Council meetings ranged from 30 to 128. The 50 Study Sections which met at that time averaged 94 applications per meeting. Twenty-four reviewed over 90 applications each, excluding the review, on an emergency basis, of large numbers of fellowship applications either at that meeting or at a special additional meeting scheduled a few weeks earlier.

Study Section workloads of 90 or more applications require that the meeting last up to four days, often going into evening sessions. Reviewers are exhausted by the end of such marathon meetings. The ability of even the most highly skilled executive secretaries to capture the substance of the review group discusson of over 90 applications at a session, accurately and in detail, must be questioned.

Executive secretaries who are best qualified to judge the effectiveness of review group performance recommend that the number of applications be adjusted to limit review sessions to no more than two and one-half days each. The Study Team regards this as an appropriate guideline in establishing workload ceilings for review groups.

Furthermore, the unremunerated effort of each review group member, in preparation for the review meetings, averages some three work weeks, or 120 hours, of detailed study and preparation of reports. The quality of a reviewer's preparation for meetings with heavy loads is visibly less complete than for meetings at which the review load per individual is appropriate to the effort (done on a reviewer's "own-time") required for careful study before the meeting.

It should be emphasized that the number of applications per review group per review session is only a partial indicator of workload and far from the definitive one. The review process also has become more complex and the following factors must be considered:

- As the increase in the NIH budget has tapered off, and competition has increased for limited grant funds, the number of reapplications also has increased.
- Research has grown more complex: the NIH receives more multi-project applications involving complex technology which are more difficult and time-consuming to review.
- Related to the above, research budget proposals must receive more scrutiny.
- Increased pressure from applicants for detailed reports of the review increases the time required to review each applicaton.
- Review procedures are more rigorous now and documentation is required in regard to the use and protection of human subjects, the appropriate use and care of research animals, the avoidance or containment of hazards to human life and health, and the environment associated with biomedical research.

- o The requirements of the "sunshine laws," discussed in another section of this report, have added to the complexity.

III. RECOMMENDATIONS AND DISCUSSION

1. THAT THE DIRECTOR, NIH, TAKE IMMEDIATE STEPS TO LIMIT THE WORKLOAD OF ALL INITIAL GRANT REVIEW GROUPS TO A LEVEL WHICH IS COMPATIBLE WITH MAINTAINING THE HIGH QUALITY OF PEER REVIEW.

   The excessive review workloads imposed on a number of DRG Study Sections and some special review groups in the awarding Institutes and Divisions of NIH must be adjusted downward. Figure 1 illustrates the workload trend for DRG. The remaining recommendations address the implementation of Recommendation 1.

2. THAT AUTHORITY TO ESTABLISH OR DISCONTINUE INITIAL GRANT REVIEW GROUPS, AS THE PEER REVIEW WORKLOAD DICTATES, SHOULD BE DELEGATED TO THE DIRECTOR, NIH.

   Congress has given the Director of the National Cancer Institute authority to establish advisory groups(2). This authority should also be provided to the Director, NIH, to enable the NIH as a whole to respond most effectively to increasing peer review loads and changes in the review workload within scintific and medical fields.

   Although trends do become apparent over time, it is not possible from one grant application receipt date to the next to predict with any accuracy which program areas will stimulate large numbers of applications. The BIDs announce program opportunities through Requests for Applications (RFAs) at irregular intervals and scientific events also stimulate new research efforts in previously dormant disciplines or fields. A small number of special applications at each review round cannot be assigned to a standing review group, either because of the unusual nature of the proposed project or activity, or because the application is submitted by a review group member and must be specially reviewed to avoid a conflict of interest situation. For these applications, ad hoc review groups must often be used. If the Director, NIH, could establish and dissolve review groups, as recommended, use of review groups for the short-term would be more feasible.

3. THAT ADDITIONAL RESOURCES BE PROVIDED FOR PEER REVIEW OF GRANT APPLICATIONS WHERE ACCEPTABLE ALTERNATIVE APPROACHES TO REDUCTION OF WORKLOAD WILL NOT PERMANENTLY AND EFFECTIVELY RESOLVE LONG-STANDING REVIEW OVERLOADS.

   Where the pool of potential review group members is adequate, existing review groups which are chronically overloaded should be "split" to form two or more groups as needed. This should be done at once.

The Study Team recognized that the organization required for peer review procedures cannot be expanded indefinitely. However, no alternatives could be identified which, at present, could be substituted for the additional staff support needed to maintain the quality of review.

4. THAT THE DIRECTOR, NIH, ESTABLISH A PERMANENT MECHANISM TO DETERMINE AND ENSURE AN APPROPRIATE CEILING OR MAXIMUM WORKLOAD FOR EACH NIH INITIAL GRANT REVIEW GROUP.

As the upward trend in average number of applications per DRG Study Section illustrates (Figure 1), the NIH has traditionally expected review groups to review whatever proposals are received by a given receipt date. In the past, allowances have not always been made for possible limits imposed by other responsibilities of review group members, or the effects of fatigue. The Study Team recommends that the importance of these factors be recognized explicitly, and that appropriate ceilings on application loads be set based on NIH review staff experience, in a centrally managed periodic review. Once established, NIH policy should require that these ceilings be honored.

The Study Team has drawn upon the recommendations of the NIH Executive Secretaries Review Activities Committee (ESRAC) and the suggestions of ESRAC workshop participants in formulating this proposal(1). Because each type of application requires a different level of effort, and because applications in different disciplines may be more or less time-consuming and difficult to review, ceilings can only be determined individually for each group.

5. THAT THE NIH CONSIDER WHETHER THERE ARE PEER REVIEW SERVICES TO NIH STAFF, ADVISORY COUNCILS, OR APPLICANTS WHICH MIGHT BE CURTAILED IF ALL OTHER WORKLOAD REDUCTION ALTERNATIVES SHOULD FAIL.

The NIH has continued to expand the services derived from or related to the peer review process for grant applications, in recent years, in the face of diminished resources and increasing review workloads. These services include providing the detailed technical information of review group critiques to investigators; reviewing, at the next scheduled review session, all applications received by or soon after a given receipt date regardless of the workload imposed; accepting an unlimited number of reapplications for a given research proposal if the original or subsequent applications did not receive an award; and assisting applicants to assure that review groups receive the most complete application for review.

Until about 1968, when research grant funds each year were adequate to make awards for most of the applications recommended for approval by the IRGs and Advisory Councils, very few grant applicants requested detailed information about the peer review critique of their applications. Those whose applications had been disapproved had other avenues of support or alternative careers readily available to them. Since that time, as NIH funds have ceased to grow rapidly (Figure 2) and the job market for researchers and academicians has become highly competitive, applicants have a much higher stake in the peer review assessment and funding of their research proposals. Alternative sources of support are scarce. Detailed information from the review critique can possibly enable the applicant to restructure the project and compete successfully. There are more reapplications, and most unfunded principal investigators demand detailed information about the review. Reviewers and executive secretaries must work harder to provide this detailed information. While the Study Team agrees that curtailing such services or providing less useful service is undesirable, this recommendation is included to emphasize that the preservation of the quality and reliability of reviews and recommendations _per se_ must take precedence.

IV. POSSIBLE ALTERNATIVES FOR REDUCING WORKLOAD

Recommendation 5 urges that the NIH consider seriously some alternatives for controlling the review load of individual review groups and reviewers, but _only_ under circumstances where needed resources cannot be provided to reduce workload. The Study Team has reviewed possible alternatives for reducing peer review workload which are other than trivial. These are:

A. The establishment of additional review groups in order to "split" or share the workload of groups which continuously receive more applications each round than they can review effectively. This is the substance of Recommendation 3, and we urge that it be done at once, where there are sufficient numbers of qualified experts to constitute the needed new groups.

B. Provision for junior executive secretaries, preferably new health scientist administrators, to work under the direction of the executive secretary for the group. This arrangement can be a useful training device for new executive secretaries and may serve, in some cases, to reduce the duration of review sessions and each reviewer's review load. The Study Team recommends that this approach be explored.

C. Provision for editorial services in DRG, or within each BID which reviews grant applications in order to assist the executive secretaries. Such editorial support would help to assure the quality of summary statements and conformity to standard formats and other NIH requirements. _The Study Team strongly recommends that such a system be considered_.

D. Short-term use of available IRGs within or across BID boundaries when such review groups, established for specialized programs, could easily absorb additional workload.

E. Creation of Special Initial Review Groups (SIRGs). This is discussed in another section of this report.

F. Contractor-conducted peer review. There are precedents for contracting out peer review. The Office of Life Sciences, NASA, for example, has contracted in the past with the American Institute of Biological Sciences for scientific and technical merit review of research proposals. Properly staffed and oriented contractor organizations can provide peer review of high quality. Contractor staff are substituted for agency staff, and do not count against the agency position ceiling. The dollar cost of contracting out more than a small part of the NIH grant peer review operation would be significant, however, and close NIH staff overview and coordination would be required; sparing of staff positions would be partial at best.

The NIH has every reason to preserve and upgrade the present system rather than to replace it. From the Wooldridge Committee to the Rand Corporation, most groups which have studied peer review have reaffirmed the value and quality of the system. It has served as a model for other agencies and programs to emulate. The Study Team recommends that the contracting alternative be reserved for special uses with appropriate NIH overview to assure conformity to NIH peer review policies and procedures.

G. Modification of peer review procedures to permit review groups and staff to absorb greater workloads. One such change has recently been implemented; with the change to the new fiscal year, the review cycle has been lengthened from six months on the average to eight months on the average. This action, while predictably not popular with applicants, does give executive secretaries more time in which to schedule site visits and prepare summary statements. Other possible modifications are:

1. To decrease the time and effort required to review each application by staff screening and rejection of incomplete or incoherent applications; to curtail discussion of applications judged by the primary reviewers to be either excellent or without merit; to curtail or eliminate site visits; etc. Casual observers of review meetings often make such suggestions, saying, for example, that too much time is spent by the primary reviewers in reading or paraphrasing the proposed project which all have in front of them.

   The responses from executive secretaries, and from grant peer review group members (see Table 16, Page 61 of Survey Report, Supplement A), suggest that full review of each application is generally held to be more important than a rapid rate of review which might be at the expense of the quality of the review. Provided a review group is working effectively, the opportunities to spare peer review resources through such review shortcuts are very limited, and best not pursued. Further staff initiatives to cull inadequate applications might be explored.

2. To curtail staff screening of applications by executive secretaries to assure that applications are complete and clear before they go to the review groups. This service to the applicant researcher is a useful function of the executive secretary, intended to assure that the applications are fairly reviewed rather than to save time or effort. It is a valuable service which NIH review staff renders to grant application principal investigators, as workloads permit. We do not recommend, except in case or dire necessity, that this staff assistance to the applicant be curtailed or abandoned.

3. To queue applications. This practice has been proposed by DRG in the past. All applications beyond the determined review capacity per round of the assigned review group would be held to the next review cycle. The NIH has rejected this proposal in the past, adhering to a long tradition of providing prompt review for all applicants whose applications reach the NIH on or before a given receipt date. Nevertheless, it is felt that queueing is preferable to acceptance of poor quality of review since it is essential that only meritorious projects are supported. From that perspective, the NIH can afford to reject queuing or any other such heroic, distasteful measures only if alternative ways of reducing or adjusting review workloads can be invoked.

4. To reduce the number of reapplications, after an application is reviewed but not awarded. The review workload can be contained somewhat if the number of such reapplications which will be accepted by the NIH in behalf of a given individual can be limited, perhaps to one per project. Since all investigators should have every opportunity to reapply in order to obtain support and a revised application is, in essence, a new application this alternative is not acceptable to the Study Team.

   A more acceptable alternative, where an unchanged application is resubmitted with the hope that it will compete successfully for funds the second or third time around, is to forward the application for BID consideration on the basis of the application's prior merit review. Applicants usually do benefit from the evaluation of the first application, however, and second or subsequent submissions are most often revised to take advantage of information from the earlier review.

V. OTHER WORKLOAD-RELATED FACTORS

There are factors which are crucial to the quality and consistency of NIH grant application peer review to which the NIH has not addressed adequate effort in the past. To improve the efforts in these areas would require assurance that the review workload per se of executive secretaries is not so large as to preclude the involvement of these key individuals in quality control activities. These activites include:

- Formal orientation and continuing education programs, and an adequate apprenticeship period for executive secretaries before assuming full responsibility for a review group;

- An effort to assure that the peer review process is reasonably consistent across the NIH, for such matters as the interpretation and use of the priority rating procedure, the concepts of "approval" and "disapproval," and the full participation of review group members in discussion.

  The Division of Research Grants has attempted to compensate for variability in the rating behavior of Study Sections, over time, by computing "normalized" scores. This represents an effective but indirect approach to the problem which has certian limitations One direct approach would be to provide opportunities for executive secretaries to work together, to observe and learn from the review process of groups other than their own, to obtain appropriate training, and to have available information, for their own use and for their reviewers, which would provide basic definitions, review objectives, procedures, and criteria, and which would be reviewed with each new reviewing or staff member.

- Common standards and procedures across the NIH for project site visits, criteria for determining when a site visit is needed, and the content and format of site visit reports.

Many of these suggestions are discussed elsewhere in this report.

VI. THE "SUNSHINE LAWS"

The requirement for more detailed documentation of review recommendations and more careful management and retention of review information, generated by the Freedom of Information Act and Privacy Act, has increased the complexity of the peer review workload and has added somewhat to the effort required to process each application. These laws are discussed in another section of this report.

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References

1. Kaufman, A. and Schiaffino, S. Memorandum: ESRAC Recommendations from Extramural-Collaborative Retreat and ESRAC Summary Statement Workshop. (1/7/76).

2. National Cancer Act of 1971 [Public Law 92-218].

Fig. 1

TOTAL NUMBER OF APPLICATIONS (R-01 AND RCDA) REVIEWED BY ALL DRG STUDY SECTIONS (MARCH 1969 - OCTOBER 1976)

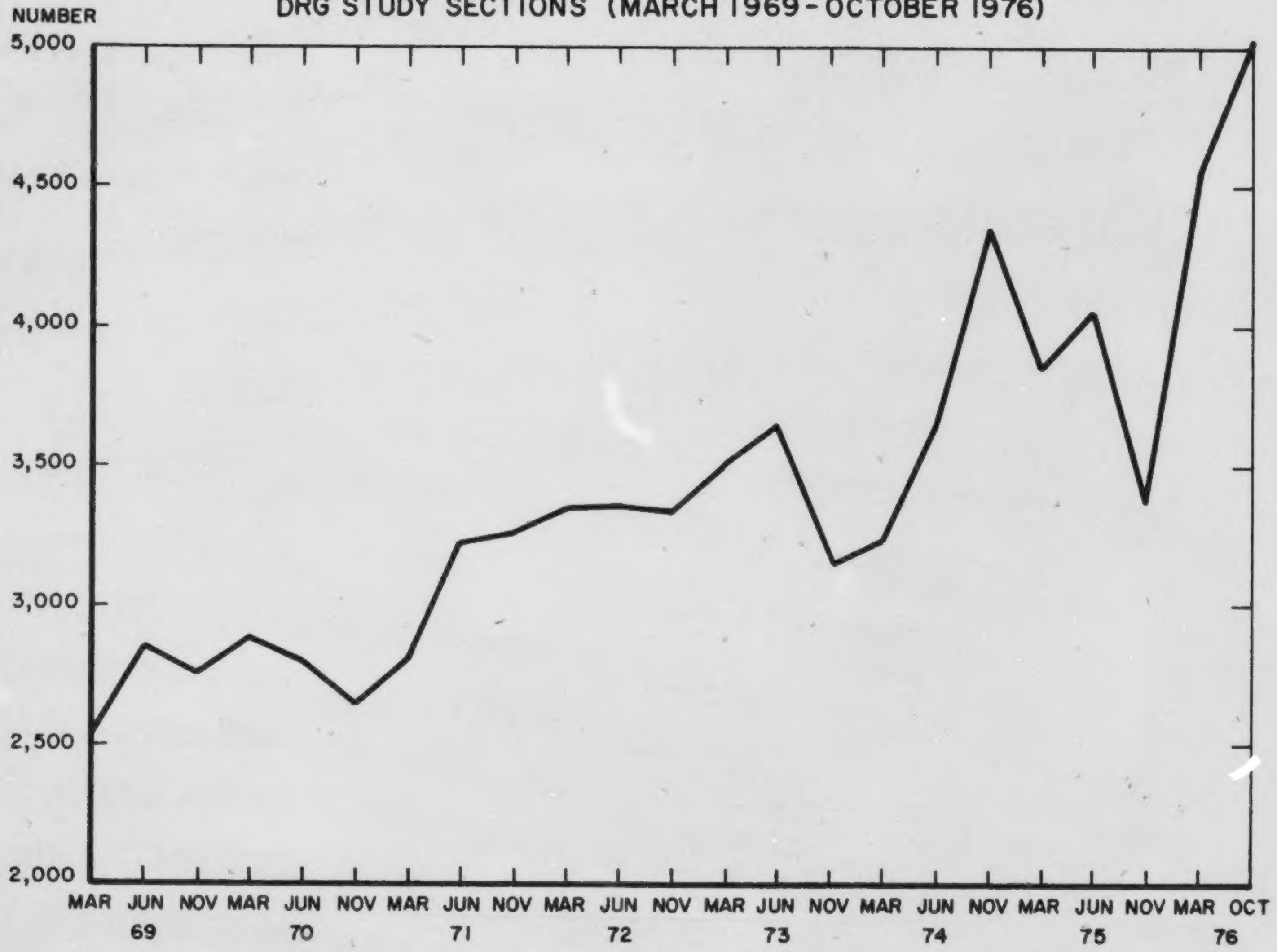


Fig. 2

AVERAGE NUMBER OF APPLICATION (R-01 AND RCDA) REVIEWED PER MEETING OF DRG STUDY SECTION (MARCH 1969-OCTOBER 1976)

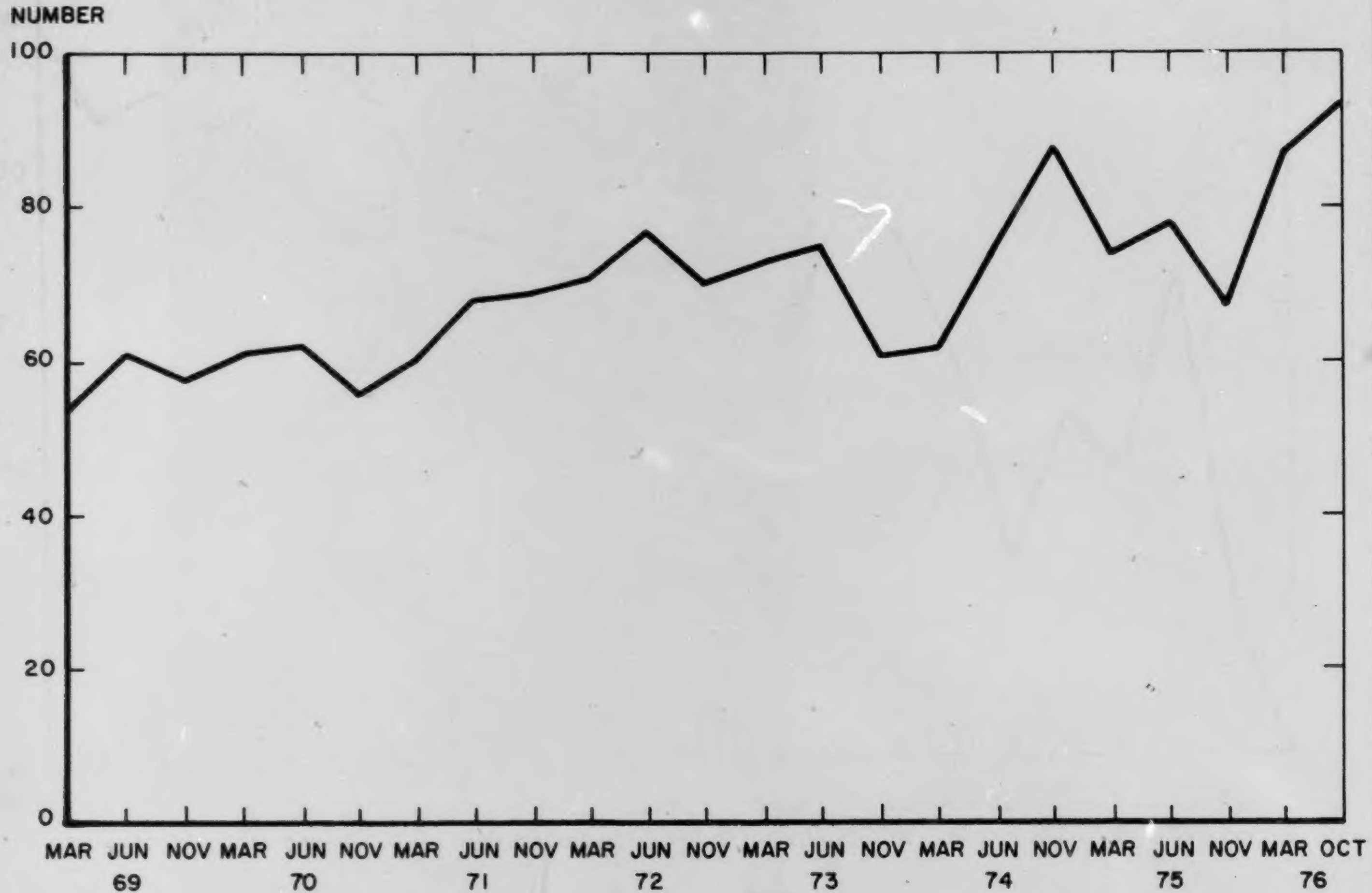
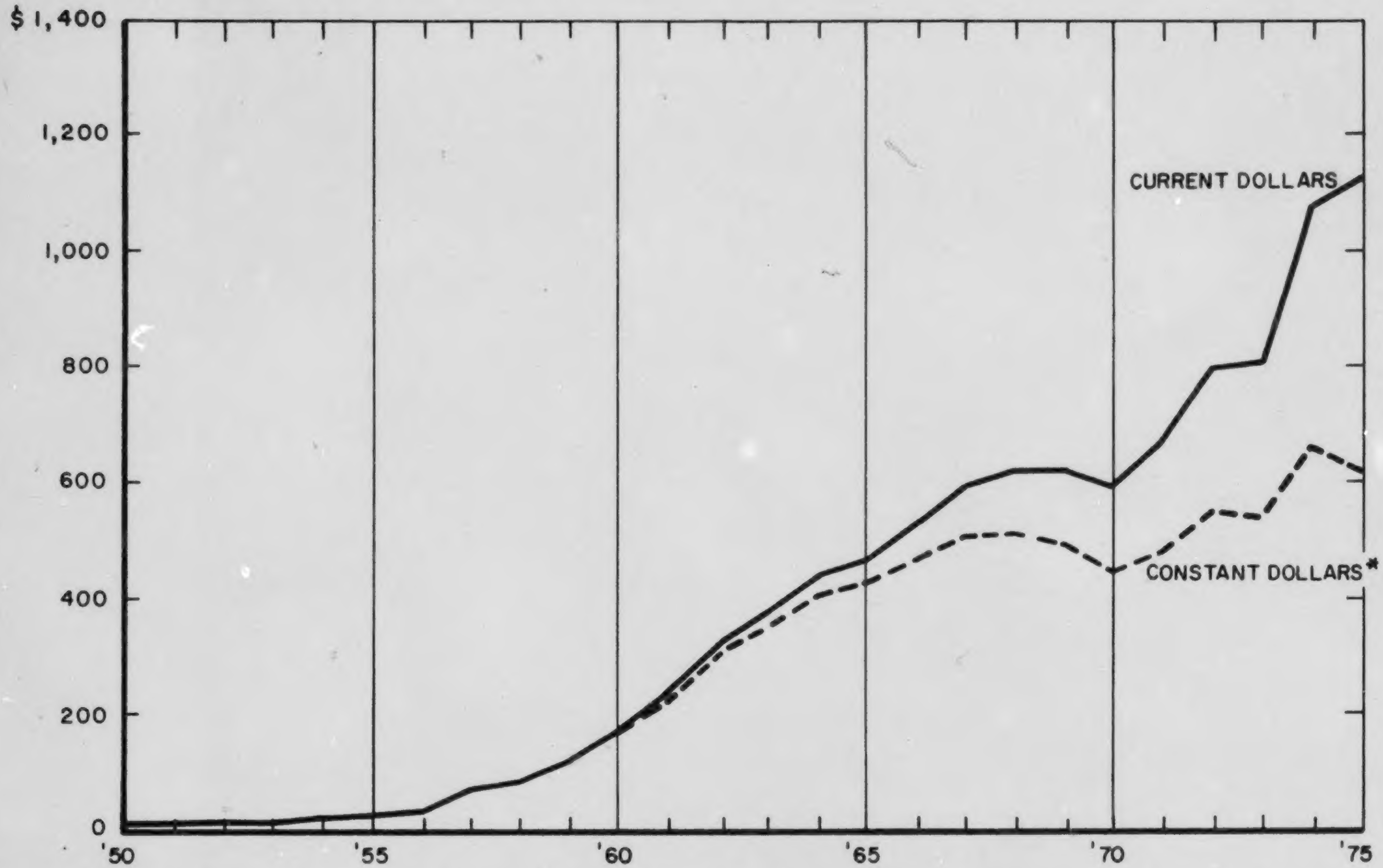


Fig. 3

NIH RESEARCH GRANT AWARDS
FISCAL YEARS 1950-1975



NOTE: NIH IS DEFINED THROUGOUT AS PRESENTLY CONSTITUTED. EXCLUDES RCP PROGRAMS.
*BASED ON THE GNP IMPLICIT PRICE DEFLATOR, FY 1958=100.
SOURCE: NIH, DRG, STATISTICS AND ANALYSIS BRANCH.

NIH-WIDE STANDARDS AND GUIDELINES FOR PEER REVIEW PROCEDURES

NIH-WIDE STANDARDS AND GUIDELINES FOR PEER REVIEW PROCEDURES

In order to provide a legal mandate for the NIH system of scientific peer review of grant applications, Congress amended the Public Health Service Act in 1974 by adding a new Section 475. This section directs the Secretary of DHEW to require, by regulation, appropriate scientific peer review of applications for biomedical and behavioral research grants under the said Act. Section 475 states that the regulations shall, to the extent practicable, require peer review to be conducted in a manner consistent with the NIH system in use at the time Section 475 was enacted, and by peer review groups performing such review on or before that date.

In accordance with the aforegoing statutory mandate, DHEW has published a notice of proposed rulemaking in the Federal Register (Appendix F-2) which sets forth proposed regulations regarding the use of and criteria for NIH grant application peer review.

Although several of the BIDs have developed guidelines for their own use, NIH-wide guidelines and standards governing specific operating procedures in peer review are incomplete. It seemed appropriate to determine whether general guidelines, applicable NIH-wide, are needed, and if so, to develop the appropriate documents. Accordingly, the Associate Director for Extramural Research and Training and the Grants Peer Review Study Team asked the Executive Secretatires Review Activities Committee (ESRAC) to conduct such a study by collecting and identifying all current written policies and procedures developed by NIH and the various BIDs and to present recommendations regarding their applicability for general use by all BIDs. The ESRAC report is due early in 1977. It is expected that it will provide NIH with the documentation necessary to determine the need for additional NIH-wide guidelines or standards beyond those already contained in the proposed regulations.

The Study Team believes that an important outcome of the ESRAC study will be the identification, for all BIDs, of the standards and guidelines utilized by particular individual BIDs, some of which may be appropriate for utilization NIH-wide. It is recognized that there may be instances which require a particular BID to have certain policies based on its own particular needs. Nonetheless, it is felt that by providing BIDs with information as to the manner in which each of them functions, all will benefit from the knowledge gained by their collective experience.

Furthermore, it is a *sine qua non* that the quality of peer review and of administrative practices followed by BIDs in regard to research grants and other award instruments is directly related to the staff which has the various responsibilities. In order to provide and maintain high quality staff activities and to assure its continued functioning at the highest level, an on-going quality control program is essential. Central to this is the need for formal training both for new staff and for those whose duties may become routine. In addition, frequent discussion groups for staff, during which open and free communication can occur are also important training experiences.

The quality of peer review is dependent not only on the professional NIH staff, but more importantly, on the advisory groups without whom the system could not function. It should be recognized that education of members of Initial Review Groups (IRGs) and Councils is essential and is a continuous process. Although guidelines are available in the form of a handbook for advisory groups, orientation sessions for both new and old members of IRGs and Councils are important in order to emphasize and reemphasize the responsibilities of each individual in regard to review and the need for group interaction.

RECOMMENDATIONS

1. THAT THE PROPOSED PEER REVIEW REGULATIONS BE FINALIZED AS SOON AS POSSIBLE.

2. THAT NIH STANDARDS AND GUIDELINES BE PREPARED OR REVISED AS SOON AS POSSIBLE AFTER CONSIDERATION AND EVALUATION OF RECOMMENDATIONS MADE IN THE STUDY BY ESRAC.

3. THAT, IN ORDER TO MAINTAIN AND IMPROVE THE LEVEL OF EXCELLENCE OF THE GRANTS PEER REVIEW SYSTEM AT NIH, A PERSONNEL POSITION SHOULD BE ESTABLISHED WITHIN THE OFFICE OF EXTRAMURAL RESEARCH AND TRAINING TO PROVIDE FOR QUALITY ASSURANCE OF THE SYSTEM. SUCH A PERSON SHOULD HAVE STAFF RESPONSIBILITY FOR MATTERS PERTAINING TO THE FORMULATION, DEVELOPMENT, INTERPRETATION, AND APPLICATION OF POLICIES RELATING TO THE ASSIGNMENT AND OVERALL SCIENTIFIC AND TECHNICAL REVIEW OF RESEARCH GRANTS AND MANPOWER DEVELOPMENT PROGRAMS.

4. THAT TRAINING CURRICULA BE DEVELOPED BY NIH FOR EXTRAMURAL PROGRAM AND REVIEW STAFF IN ORDER TO PROVIDE ORIENTATION AND TO REFRESH AND REITERATE PRINCIPLES CONCERNING THE PHILOSOPHY, OBJECTIVES, AND PROCEDURES FOR PEER REVIEW.

5. THAT OPEN FORUMS AND WORKSHOPS FOR PROGRAM AND REVIEW STAFF BE ESTABLISHED ON A CONTINUING BASIS SO AS TO ENCOURAGE AND IMPROVE EXCHANGE AND COMMUNICATION OF IDEAS CONCERNING ISSUES RELEVANT TO THE PEER REVIEW SYSTEM.

6. THAT THE DIRECTOR, NIH, THE BID DIRECTORS, AND THEIR STAFFS HOLD ORIENTATION SESSIONS ANNUALLY FOR ALL IRG AND COUNCIL MEMBERS, PARTICULARLY NEW MEMBERS, IN ORDER TO PLACE PEER REVIEW IN PERSPECTIVE AND TO INFORM REVIEWERS OF THEIR FUNCTIONS, DUTIES, AND RESPONSIBILITIES.

NIH-WIDE STANDARDS AND GUIDELINES FOR PEER REVIEW PROCEDURES

References

1. Orientation Handbook for New Members of Study Sections. Division of Research Grants, National Institutes of Health (1976).

PEER REVIEW OF PROGRAM PROJECT AND CENTER GRANTS

PEER REVIEW OF PROGRAM PROJECT AND CENTER GRANTS

Peer review procedures for program project and center grant applications have received and continue to receive intensive examination by NIH staff to assure that the same general principles of review are followed for the complex large grant applications as for the traditional investigator-initiated research grant application.

The perceptions of the biomedical community regarding program project and center grants focus on a number of issues, some of which relate to peer review of such grant applications and others which are more peripherally, if at all, related to peer review. Of those who addressed the issue of program projects and center grants in letter responses to the Study Team or in testimony at the public hearings, the following concerns were most frequently mentioned:

(a) the poorer quality of peer review of program project and center grant applications as compared to that of the traditional scientific research grant applications;

(b) inadequate separation of review and program functions among BID staff which leads to bias in the review as a result of pressure in reviewer selection;

(c) the appearance of conflicts of interest for or against a program project or center grant among site visitors reviewing such applications;

(d) adequate balance of funds between traditional and program project and center grants and the increasing allocation of funds for the latter;

(e) the lengthy duration of committed support for program project and center grants, thus closing off funds available for initiation of new regular grants.

NIH review group members also were concerned about the adequacy of the review of program project and center grant applications. The survey questionnaire revealed that, whereas 97% of the respondents thought that the review of traditional research grants was excellent or good, a significantly lower percentage (78%) of the respondents thought that the review of program project and center grant applications was excellent or good (Supplement 1).

The proportion of research grant funds awarded for program projects and centers varies considerably among the BIDs. Nevertheless, it should be pointed out that, in FY 1976, all BIDs except the Division of Research Resources (DRR) and the National Institute of Environmental Health Sciences (NIEHS) awarded more than half of their research grant funds for individual research projects. The National Institute of Allergy and Infectious Diseases (NIAID) and the National Eye Institute (NEI) awarded 91% of their research grant funds for research projects, followed by the National Institute of Arthritis, Metabolism and Digestive Disorders (NIAMMD), 87%; National Institute of General Medical Sciences (NIGMS), 77%; National Institute of Child Health and Human Development (NICHD), 72%; National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), 68%; and the National Institute of Dental Research (NIDR), 61%. The National Cancer Institute (NCI), 59%; National Heart, Lung, and Blood Institute (NHLBI) 54%; and the National Institute of Aging (NIA), 54%, awarded slightly more than one-half of their research grant funds for research projects. The NIEHS divided its awards almost evenly between research projects and program projects and centers. Almost all of DRR research grant funds (excluding General Research Support Grants) were awarded for center grants reflecting the particular mission of that organization.

Peer review procedures for program project and center grant applications have been the subject of a further recent study by an NIH staff group (Appendix G). Other studies are also in progress to examine a series of issues relevant to these complex grants. The concerns expressed by the biomedical community reinforce the Study Team's recommendation that the aforementioned studies be continued. In addition, it is strongly recommended that there be strict adherence to the principles of peer review in order to assure the highest quality of review for these complex grants.

PEER REVIEW OF PROGRAM PROJECT AND CENTER GRANTS

References

1. Subcommittee Report on Peer Review of Large Programs at the NIH. (Program Project and Center Grant Task Force) (1975).

2. Report of the Termination Subcommittee and Report of the Subcommittee on Utility and Effectiveness. (Program Project and Center Grant Task Force) (1975).

3. Report of Institutional Profiles Subcommittee. (Program Project and Center Grant Task Force) (1974)

4. Report of the Subcommittee on Management Practices. (Program Project and Center Grant Task Force) (1973).

REVIEW OF BUSINESS MANAGEMENT PRACTICES

REVIEW OF BUSINESS MANAGEMENT PRACTICES

In developing its assessment of the peer review process and preparing its report, the Grants Peer Review Study Team (GPRST) felt that a study of review procedures, particularly for large, complex, multifaceted grants, in regard to the business management practices of the institutions applying for such grants was essential. Accordingly, a subcommittee on business management practices was established and performed an in-depth study which is endorsed by the GPRST and is incorporated in this section.

I. Background

The Subcommittee was charged with the responsibility of studying all aspects of the business management issues associated with the peer review process and making recommendations based on its findings.

In considering various approaches to meeting the assignment, the Subcommittee, in its first two meetings, made several basic determinations, such as:

A. Since the issue at hand concerned peer review and not staff review, the study would actually deal primarily with the NIH use of outside business management consultants at the level of the initial review group or project site visit team. As intended here, the term, business management consultant, relates to any individual who, because of background--training and experience--is qualified to provide expert evaluation and advice in assessing grantee institutional business management systems/areas such as fiscal administration, budget planning and execution, personnel, procurement, facilities management, property, etc.

B. The grant applications that do feature or would appear to require business management input as a part of the peer review process would generally be of the program project and center types or those involving consortium arrangements and, accordingly, the study would be essentially limited to these.

C. It was recognized that, in the initial review of the larger and more complex grants, there is often the need for input from other non-scientific reviewers whose backgrounds and expertise fall into the area of senior level program management, i.e., academic deans, etc. Further, even though there can occasionally be some overlap of program management and business management consultant review activity, depending upon individual qualifications and specific circumstances, no attempt would be made to include the role of the program management consultants in the study.

D. While substantial extramural operational background experience was present among the membership of the subcommittee, a great deal of informational input from outside would be required to develop a complete picture of the NIH involvement and/or commitment in this area.

II. Methodology

The major fact-finding activities of the group were pursued in a series of inter-related phases with the various inputs building upon one another. The primary efforts were as follows:

A. A preliminary search was made for NIH documents (Manual Chapters, etc.) which might have reference to the business management aspects of peer review and, from within the organizations represented by the membership, a collection was made of any pertinent BID peer review procedural directives or guidelines.

B. Since the above provided only an extremely limited indication of what was being done at NIH, it was determined that a standardized questionnaire should be developed for soliciting information from each of the BIDs. The questionnaire was designed to generate specific data on the extent of non-NIH business management consultant utilization (see Appendix H-1). Along with responses to eleven questions, the document requested submission of copies of any written guidelines routinely provided to business management consultants prior to participation in site visits and, also, samples of Project Site Visit (PSV) reports and/or Initial Review Group (IRG) Summary Statements reflecting specific contributions of the business consultants. The responses to the questionnaire were summarized and studied (see Appendix H-2).

C. While the data were being collected from the NIH BIDs, it was decided that an attempt should be made to obtain input on similar activities which might be involved in the review of grants by some other agencies with missions comparable to NIH. At a meeting arranged with staff of the National Science Foundation and the Alcohol, Drug Abuse, and Mental Health Administration, comments of the visitors were quite interesting but indicated that little or no business management expertise is built into the grant review processes of the two agencies (see Appendix H-3).

D. It was felt that there would be potential value in obtaining input from a representative number of individuals who have performed for NIH in a business management capacity within the grant peer review process. An all-day meeting was arranged with seven such consultants with NIH experience ranging from very extensive to comparatively limited (see Appendices H-4 and H-5).

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The session was felt to be quite beneficial, providing ample opportunity to learn much of the way in which these people view, among other things: (1) the role they are called upon to perform; (2) the degree of receptivity to their efforts; (3) the type of report which should be written; and (4) the possibility for changes in approach which might make their participation more effective.

E. Having heard extensive commentary by this group of consultants, the Subcommittee determined that it would be of interest to review two or more examples of IRG Summary Statements and Project Site Visit (PSV) reports to which each of the individuals had contributed. With the help of at least six BIDs, sixteen such documents were collected, duplicated, and reviewed. In an attempt to display possible differences in approach, examples were selected where the individual consultants had worked for different BIDs or participated in reviews of different types of grant applications.

F. Because of the important role played by the NIH Executive Secretaries in the total grants review process, it was decided to obtain input from a representative number of such NIH staff on the same issues which had been discussed with the business management consultants (see Appendix H-6). To allow for freedom of expression, arrangements were made for four separate meetings with appropriate staff responsible for review from DRG, NICHD, NCI and NHLBI. With real differences of personal opinion being shared by the Executive Secretaries, these meetings were found to be very enlightening.

G. As a final fact-finding effort, the Subcommittee decided to approach another group of individuals believed to be uniquely qualified to react to questions on the role of the business management consultant in peer review. This would be a number of senior NIH scientific consultants who have either chaired permanent or ad hoc initial review committees or project site visit teams, or both. To contact such individuals with the least inconvenience to them, it was determined that a telephone survey would be made, utilizing conference calls so that two or three Subcommittee members could speak with each of the chairmen. A standardized list of questions was developed in advance to use as a guide in querying the eight chairmen with whom conference call arrangements were made. This approach worked quite well and much helpful information was obtained (see Appendix H-7).

III. RECOMMENDATIONS AND DISCUSSION

No listing of general findings has been presented previously because each of the recommendations that follow will have an accompanying statement of rationale. These statements will include significant evidence of what was found by the Subcommittee in its various phases of information-gathering. The recommendations have been developed because of the strong conviction that the actions proposed are critically needed to formalize an NIH position on an important aspect of the grants peer review process, which, in the past, has been left largely to whim or chance. The recommendations are:

A. THAT IT BE RECOGNIZED AS AN NIH POLICY POSITION THAT THE USE OF BUSINESS MANAGEMENT CONSULTANTS AS REVIEWERS IS A NECESSARY ADJUNCT TO THE SCIENTIFIC REVIEW OF THE LARGE, COMPLEX AND MULTIFACETED PROGRAM PROJECTS, CENTERS, OR THOSE GRANTS INVOLVING CONSORTIUM ARRANGEMENTS.

The evidence developed through the questionnaire indicates that the use of such consultants in the review of program project and center grant applications ranges across the multiple BIDs from "never" to "almost always." These are perhaps not equal extremes, but it is concluded that NIH should present more of a reasonable "middle ground" picture on this issue with, at least, no BID being permitted to determine on its own "never" to avail itself of the benefit of such management expertise. The discussions with the business management consultants, the Executive Secretaries, and the IRG or PSV chairmen provided ample support for the basic value of augmenting the highly specialized scientific review with appropriate evaluation of business management practices.

B. THAT THE PRINCIPAL CRITERIA USED TO DETERMINE THE NEED FOR BUSINESS MANAGEMENT CONSULTANT SUPPORT BE RELATED TO THE ORGANIZATIONAL OR ADMINISTRATIVE COMPLEXITY EXISTING IN ANY PARTICULAR GRANT APPLICATION.

This recommendation is based on the understanding that there is no simple way of determining when it would be appropriate to utilize business management expertise in reviewing an application. Certainly, sheer size of the program or proposed dollar level cannot be used as hard and fast criteria. It is in keeping with the many inputs received to say that each application must be reviewed on its own with a judgmental determination being made as to complexity.

C. THAT, CONSIDERING THE NATURE OF THE TRADITIONAL INVESTIGATOR-INITIATED RESEARCH PROJECT APPLICATION AND ITS REVIEW, IT BE RECOGNIZED THAT THE USE OF BUSINESS MANAGEMENT CONSULTANTS WOULD NOT USUALLY BE CONSIDERED NECESSARY OR APPROPRIATE.

Such a position was uniformly held by all individuals consulted. However, it was expressed with the understanding that the individual research grant application could represent a very large and complex project, particularly if it involved a consortium arrangement, and might be equally in need of expert business management review.

D. THAT NIH DEVELOP A POLICY ISSUANCE CONCERNING THE ROLE OF AND NEED FOR ASSESSMENT OF BUSINESS MANAGEMENT IN THE REVIEW OF THE LARGE PROGRAM PROJECT AND CENTER GRANT APPLICATIONS.

Along with the three previous recommendations, this is a natural follow-up since there is currently no NIH policy which speaks to the issue of business management review. It is felt that most of those consulted endorse such a proposal as long as there is no attempt to narrowly define the circumstances under which management consultants are to be used in the peer review process.

E. THAT NIH DEVELOP UNIFORM GUIDELINES TO BE FOLLOWED BY THE BUSINESS MANAGEMENT CONSULTANTS IN THEIR ROLES AS MEMBERS OF PROJECT SITE VISIT TEAMS AND ADVISORY GROUPS.

In spite of the extensive use of business management consultants by certain components of NIH, there have never been any NIH-wide guidelines developed to indicate what is expected of them. Those with whom the Subcommittee met indicated that they had developed their own approaches to doing the job and were sometimes left wondering whether they were turning in a satisfactory piece of work. The Executive Secretaries and PSV chairmen confirmed that they provided little verbal guidance, if any, to the business management consultants. As might be expected, the review of multiple summary statements and PSV reports indicated vast differences in approach. There was a uniformly positive response from all quarters to the idea of NIH guidelines being developed.

1. That the consultant's function should be to review and recommend primarily on the adequacy of business management practices and arrangements (including soundness of budgetary planning) for the program project or the center itself.

2. That the business management consultant normally should not be concerned with exploring the history, current financial status, or administrative adequacy of the institution as a whole unless special situations call for it.

3. That, in following the standard site visit approach of separating away from the scientific review, the business management consultant should concentrate on dealing with institutional/administrative staff members who will be directly involved with the project.

4. That flexibility should be permitted so that, depending upon the individual and the specific circumstance of his/her participation, the business management consultant could be asked to contribute to other administratively oriented aspects of grant application review, such as proposed

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procedures for decision-making and resource allocation within a program project or plans for controlling access to and use of shared facilities and services in a core center or resource grant.

E.1, 2, 3, and 4 have been tied together because of similarity and relationship to the basic recommendation E concerning development of performance guidelines for the business management consultant. These four recommendations present new concepts which are based on general concurrence from the group of administrative consultants. Regardless of the historical background for it, some of the BIDs have been responsible for fostering an institutional review approach on the part of the management consultants which frequently expends much of their effort in areas of little profit. It is apparent that the great bulk of the large grants are awarded to the larger and well established institutions. Further, in looking at the "large grants" picture, it is understandable that many of these institutions might have as many as 10, 20, or more competitive reviews on the large grant applications each year. Therefore, as a general rule, it may be safe to say that there is little real value in having the consultants devote significant time to interviewing top institutional officials, i.e., presidents, vice-presidents for administration or research, comptrollers, etc., and writing much into their reports on institutional history, financial status, and administrative adequacy. It is felt that there is a very important role for the consultant in evaluating thoroughly various business management aspects of the level of the program project and/or center itself. This may mean dealing extensively with a number of mid-level management officials, but this is where the real knowledge on the extent of planning and proposed operational approaches can be obtained. It is also the level where the consultant may be able to provide some real assistance to the grantee staff in making suggestions on how to overcome identified inadequacies or proposing alternative approaches in areas where he might feel it appropriate. It is clear that there is a need for maximum benefit to be obtained from the participation of qualified management personnel. However, another misuse practiced by some of the BIDs should be mentioned. From a review of summary sheets/PSV reports and from the comments of the business management consultants themselves, it is apparent their maximum efforts are, at times, directed toward tracking and recording the multiple budgetary adjustments made in the course of a PSV on the large grants. Such activity, when combined with the more responsible role, is acceptable; but, if it is considered as the primary reason for having such individuals participate in the review, then this represents a serious misuse of such expertise.

F. THAT BUSINESS MANAGEMENT CONSULTANTS SHOULD CONTRIBUTE TO OVER-ALL RECOMMENDATIONS ON PROJECT SITE VISITS AND AT INITIAL REVIEW GROUP MEETINGS, BUT THEY SHOULD NOT VOTE ON "APPROVAL VS DISAPPROVAL" OR GIVE A PRIORITY RATING UNLESS, IN THE JUDGMENT OF THE EXECUTIVE SECRETARY, THE TYPE OF PROJECT INCLUDES SIGNIFICANT NON-SCIENTIFIC ASPECTS CLEARLY WITHIN THEIR PROFESSIONAL EXPERTISE.

The question of voting was a very intriguing one. The business management consultants themselves were somewhat ambivalent on the question of whether they should vote. There was an indication that some abstain from voting even though they are almost routinely asked to do so. Recognizing that the peer review is clearly an overall evaluation of scientific merit, an attempt was made to determine the basis on which the management consultants would vote. It was felt that, if the vote was based primarily on their administrative evaluation, this would be questionable; if they were voting on what they thought was a consensus of the scientific reviewers' opinions, this would also be questionable, but for vastly different reasons. It was difficult to get any kind of uniform response from the management consultants, so the question was also raised with the Executive Secretaries and the committee chairmen. Here, the question was more difficult because they were being asked to speculate on the basis of the management consultant's vote. The responses were even more variable, but generally led to a discussion of the fact that it really did not matter because the management consultants represented such a limited minority in the typical voting situation that their individual vote would have no impact anyway. Many of the chairmen reversed their previously stated position that the management consultants should have the vote when asked how they would feel if the total participation in the review activity involved only six or seven individuals, rather than 16 to 22. The strong feeling developed that, while the management consultants could provide significant input or findings worthy of serious consideration by the whole group of scientific reviewers in looking at the total application package, the business consultants should not have the option to vote. An exception to this rule would be made if the Executive Secretary of the IRG or PSV team makes a determination that the nature of the project includes significant non-scientific aspects clearly within the professional expertise of the business management consultant. In this case, the consultant could exercise a full vote on approval vs disapproval and on the priority score.

G. THAT BUSINESS MANAGEMENT CONSULTANTS SHOULD PREPARE A SPECIFIC PORTION OF PROJECT SITE VISIT REPORTS AND/OR IRG SUMMARY STATEMENTS WHICH SHOULD BE RECOGNIZED AS SEPARATE FROM SCIENTIFIC REVIEW AND EVALUATION, BUT SHOULD BE CAREFULLY CONSIDERED IN REACHING RECOMMENDATIONS FOR EACH PROJECT

This recommendation is closely related in some ways to the previous one on the "vote." Again, recognizing the basic responsibility for scientific merit assessment by the initial reviewers, it was felt that the business management evaluation should be kept distinct from the scientific evaluation. The business management consultant's portion of the report could be critical to the overall judgment exercised by the scientific reviewers of the total program, but it should be clearly separate from the scientific critiques of program segments. Most of those individuals questioned agreed completely with this position.

H. THAT PROCEDURES BE DEVELOPED WHICH WOULD ALLOW THE REPORTS OF THE BUSINESS MANAGEMENT CONSULTANTS, INCLUDING SPECIFIC RECOMMENDATIONS FOR MANAGEMENT IMPROVEMENT, TO BE MADE AVAILABLE TO THE APPLICANT INSTITUTION BY THE BID AT AN APPROPRIATE TIME AFTER COMPLETION OF THE REVIEW.

This recommendation relates to the rationale for E.1, 2, 3, and 4 (content) and G (format) above. With appropriate guidelines for the management consultants, it is felt that many more reports (than are currently seen) could provide significantly helpful advice for the management staff of the grantee institutions. If this is the case, then that information should be readily transferable by staff of the awarding component to appropriate personnel at the institutions where it could be utilized. Implementation of this recommendation is not now proposed, but rather it is suggested that a standardized report formating or other ideas should be considered to make this recommendation feasible. The grants management officer should be responsible for coordinating this activity within the BID.

I. THAT GRANTS MANAGEMENT OFFICERS OF THE BIDs PARTICIPATE WITH THE IRG EXECUTIVE SECRETARIES IN THE DETERMINATION OF A NEED FOR, AND IN SELECTION OF, BUSINESS MANAGEMENT CONSULTANTS FOR THE PROJECT SITE VISIT TEAM INVOLVEMENT.

Under recommendation B, reference was made to the fact that the need for business management consultant support should be related to the organizational or administrative complexity of the individual grant application. With the grants management officers' background experience and concerns for smooth pre- and post-award administration, and the fact that they sometimes have different ways of looking at issues (from program management staff), it seems reasonable and logical to propose their participation with the Executive Secretaries in making the determination of need. Likewise, because of their continuing day-to-day involvement with business management staffs of grantee institutions, it was felt that they could be particularly helpful in selection of the business management consultants.

J. THAT, WHENEVER POSSIBLE, BID GRANTS MANAGEMENT STAFF MEMBERS SHOULD ACCOMPANY THE SITE VISIT TEAMS ON THE REVIEWS OF THE COMPLEX PROJECTS, SERVING AS STAFF RESOURCES ONLY.

This recommendation came primarily from discussions with the Executive Secretaries and the IRG/PSV chairmen. Some feeling was expressed that grants management staff could serve in lieu of business management consultants, performing the same role, except that they would not be considered as actual members of the PSV team and, of course, would not vote. However, the majority did not favor this approach for a variety of reasons, not the least of which was related to a possible conflict of interest. Here, an analogy was drawn to the impropriety of utilizing an extramural BID program manager as a scientific reviewer. Perhaps a more practical reason for negativity was based on the belief that the grants management staff were, in general, not experienced in grantee institution management and could not really do the same type of job as the business management consultant who "knew the territory" and would be able to "open necessary doors." While agreeing, it was felt that the basis for the above recommendation is: (1) that the grants management staff can and do serve as very valuable staff resources because of their intimate knowledge of grants policies and procedures; and (2) that the firsthand exposure to the institutional staff, facilities, and environment at the time of review would provide the grants management staff with many insights which could be of great value in carrying out later administrative responsibilities in the event a grant is awarded.

IV. Conclusions

In FY 1975, NIH obligated approximately $416 million for large program project and center grants. It is clear that NIH-wide policies and procedures should be developed specifying business management techniques to be employed in the grant peer review process. At present, no such directives exist and BID Executive Secretaries, business management consultants, and IRG or PSV chairmen have no uniform guidance in this important area.

THE ROLE OF PEER REVIEW IN SUPPORT OF UNORTHODOX, INNOVATIVE RESEARCH

THE ROLE OF PEER REVIEW IN SUPPORT OF UNORTHODOX, INNOVATIVE RESEARCH

In any process dealing with the support of research and development there must be provision for the identification of unusual and innovative approaches. Creative and unorthodox avenues of investigation may herald great leaps forward in concept; they may represent a turning point in research directions; or they may, all too often, be fruitless attempts to overcome obstacles to further progress.

I. DISCUSSION

Within NIH, as in the medical and scientific community at large, there is concern that the peer review system favors the support of traditional, conservative, orthodox research and that this is at the expense of innovative, unorthodox research. This perception is further complicated by the view held by many that innovative, especially creative research, is usually conceived by young investigators whose research ideas are usually untried, may not be well received and the significance of which not even be recognized. Consequently, such research applications are frequently disapproved or, if approved, at a priority which is not fundable. We are certain that this course of events does occur but we do not know how often and in what circumstances it is most likely to occur. Moreover, the Study Team does not believe there is any ineluctable relationship between youth and creativity.

One of the criteria used by IRGs in their scientific and technical merit review involves an assessment of the probability of success of the proposed project. If the concept is truly innovative and if the approach to the problem is unorthodox, then the reviewers are confronted with a dilemma. A proposal that involves an idea that is innovative or unorthodox requires an assessment of probable success and this may assume even greater weight and significance. Often, the evidence indicating probable success is limited and, therefore, many such applications are not recommended with enthusiasm. And yet, most reviewers are truly eager to find, identify, and recommend support for fresh new ideas. If an application contains a new or even unconventional approach to a problem and if it is well conceived in its component elements, IRGs will generally recommend support even though they believe that the likelihood of probable success may be marginal. Indeed, this eagerness may lead to a generous assessment of probable success in order to assure a favorable recommendation for support. If, however, the proposal is poorly conceived and/or inadequately prepared, IRGs are less likely to make a generous or favorable assessment of probable success of the project, and the ultimate recommendation may well be disapproval. Thus, in these circumstances, the applicant would seem to have a special responsibility to write clearly, explain fully, and, if possible, report the results or trends of pilot studies. In short, to compete successfully the innovative and unorthodox proposal should be buttressed by an especially well prepared application.

It should be noted that the NIH mechanisms of research support represent investments designed to attain a better understanding of disease processes that may lead ultimately to improvements in health. They do not represent investments in individuals only, in people *per se*—even those who are expecially creative and innovative. The investment is in people only to the extent that they conceive research ideas that may lead to the aforementioned results.

The membership of NIH peer review groups is seen by some as a force tending to preserve orthodoxy. The members are selected because of their competence in research, their contributions to biomedical knowledge, their stature, and their willingness to devote long hours to these arduous review tasks. Some believe that, by definition, they are "the establishment." They represent, in the aggregate, the current state of the art, the current vanguard of research—but not tomorrow's. These tendencies toward orthodoxy do indeed exist but they are offset by several factors: the efforts to have IRGs reflect a broad range of research viewpoints; the appointment of constructive, critical, enthusiastic investigators to review groups; the deliberate attempts to have outstanding young investigators on initial review groups; and the eager competition within review groups to detect and recognize the innovative, unorthodox proposal that may open new and promising avenues of investigation.

Certainly, the most subtle and most pervasive influence that fosters the support of safe, orthodox research, as opposed to the creative and innovative, is the limited availability of funds. As the dollars available for research support become more and more limited, there is a tendency (almost inevitable and often uncontrollable) to invest in the "safe bet." In such circumstances, advisors, consultants, staff members, and program managers avoid the high risk, the nonconformist, innovative proposal. Indeed, chronic or recurrent shortages of funds may indicate, and may cause, the demise of a truly vital research program.

Because so many individuals associate especially creative, innovative research with new and/or young investigators, the question of peer review as it relates to the support of new investigators is relevant here. Data derived from the study conducted by Douglass and James(1) indicate that, for the period from 1966 to 1972, approximately ten percent of all principal investigators on research project grants were being supported by NIH for the first time. Unpublished data for the period, 1972 to 1975, indicate that the percentage has remained about the same: about 53 percent of all new research project awards were received from investigators entering the NIH competitive system for the first time. Furthermore, in most Institutes the success (i.e., funding) rate for the younger investigators is better than that experienced by the older applicants. It should be noted, however, that the most critical and useful index for the success of the peer review system is the quality of research that has been supported over the years, and the advances in our knowledge which have come about from such support.

How can the especially innovative research proposal be identified? Those who submit what they consider to be creative, unorthodox research applications should be encouraged to identify their research as innovative; they should be required to state clearly and to document fully the innovative aspects of their proposal and the significant consequences that may emerge if support is provided.

The Study Team is of the opinion that the initial review groups have a particular responsibility in the identification of this type of innovative research. This requires perception, reflection, and the provision of adequate time for discussion. It is not easy to accomplish in circumstances where a review group is overburdened and tired. It is convinced that the IRG members are truly dedicated to such efforts. In fact, they seem to share the joy of discovery when they can identify and describe the creative insight, the new approach, or the truly innovative proposal. They are men and women of broad vision who are anxious to ensure that the present system provides for the adequate recognition and support of innovative research.

II. RECOMMENDATIONS

1. THAT NIH REQUIRE THE APPLICANT TO IDENTIFY AND SUPPORT IN DETAIL THE CONTENTION THAT THE RESEARCH PROJECT BEING PROPOSED IS ESPECIALLY INNOVATIVE;

2. THAT INITIAL REVIEW GROUPS BE REQUESTED TO IDENTIFY APPLICATIONS THEY CONSIDER TO BE ESPECIALLY CREATIVE OR INNOVATIVE, WHETHER OR NOT THE APPLICATIONS WERE SO IDENTIFIED BY THE APPLICANT;

3. THAT IRG MEMBERS (AS A GROUP OR INDIVIDUALLY) BE ENCOURAGED TO PREPARE A STATEMENT IN ADDITION TO THE REGULAR SUMMARY STATEMENT POINTING OUT THE INNOVATIVE ASPECTS OF THE APPLICATION AND ITS SIGNIFICANCE. THIS STATEMENT IS TO BE PREPARED REGARDLESS OF WHETHER THE APPLICATION WAS RECOMMENDED FOR APPROVAL OR DISAPPROVAL; THESE APPLICATIONS WILL BE FLAGGED FOR SPECIAL CONSIDERATION BY BID STAFF AND/OR ADVISORY COUNCIL;

4. THAT NIH CONSIDER THE FEASIBILITY OF DEVELOPING AN EXPERIMENT INVOLVING LIMITED SUPPORT FOR CERTAIN SPECULATIVE, HIGH-RISK, INNOVATIVE RESEARCH PROPOSALS. SUCH A STUDY MIGHT BE PART OF A LARGER, MUCH-NEEDED EFFORT TO EXAMINE THE PROCESSES OF DECISION-MAKING IN ALLOCATING RESEARCH SUPPORT.

ROLE OF PEER REVIEW IN SUPPORT OF UNORTHODOX INNOVATIVE RESEARCH

References

1. Douglass, C. D., and James, J. C. Support of New Principal Investigators by NIH: 1966 to 1972. Science 181: 241-244 (1973).

COMMUNICATIONS WITH APPLICANT-INVESTIGATORS AND DOCUMENTATION OF REVIEW RESULTS

IMPACT OF INAPPROPRIATE DISCLOSURE OF REVIEW DELIBERATIONS

The dual peer review process, and the decision-making process, have been described in previous sections and will not be restated here. In addition, the impact of the Privacy Act on the peer review process has been discussed in detail. The implications of this Act are that the principal investigator has a right to a complete and detailed explanation of the review and decision concerning his/her application. However, this explanation must be accurate and reflect the final critique as prepared by the Executive Secretary of the particular IRG involved.

Final formal action on an application is taken only after a number of steps in the review and decision-making process have occurred. No one action along this orderly path can be considered binding until the final Institute position has been offically conveyed to the applicant-institution and principal investigator.

Unauthorized premature disclosure of the results of any portion of the total review process may cause serious and unnecessary problems. Thus, a potential grantee cannot assume that an award will or will not be made based on a rumor or on casual comments by persons involved in the review process or by NIH review or administrative (program) staff. Such comments are inappropriate, and if made or if rumors are circulated, applicants do expect certain actions to occur. For this reason, the proceedings of review meetings, the discussions which were held, the preliminary results of a site visit, the written preliminary comments of the assigned reviewers, are all considered as confidential working materials; they must not be discussed openly by those involved in the review or by the staff, with the applicant-investigator, or with any other unauthorized persons.

It is obvious that there are many points during the process at which premature disclosure can occur. For example, if a project site visit is performed as part of a large review, the report which is prepared for submission to a parent initial review group, is clearly preliminary and must be considered a working document. The written comments of assigned reviewers and outside consultants, similarly, are preliminary working documents. After full discussion at an IRG meeting, the essence of the roundtable discussion and the salient features on which recommendations are based, are incorporated into the summary statement prepared by the Executive Secretary. Again, it should be emphasized that the preliminary evaluations may be significantly changed as a result of additional information and discusson during the meeting, and are not necessarily reflected in the final summary statement. Once the relevant portions of the working documents (individual preliminary reviews, site visit reports, etc.) have been used for the preparation of the official summary report, they are of no further use or significance and thus should not be retained.

Furthermore, it often happens that an Advisory Council/Board may recommend, and an Institute may make, an award for a grant which was recommended for approval by the IRG with only moderate enthusiasm but which involves studies within an area of high program interest to the BID. Conversely, a grant application which has been approved with a high priority score may have to wait for funding if other program priorities take precedence and there are limited funds available. Thus, even the summary statements prepared by IRGs do not reflect final BID action but only the IRG recommendation.

It is therefore esstential that confidentiality be maintained by those persons involved in the review and the administrative details of the process so that the applicant-investigator obtains the appropriate and accurate information.

The Study Team recommends that NIH reiterate its policy that all persons involved in grants peer review be constantly alert concerning the need for confidentiality of all aspects of the review, and that there be strict adherence to the policy concerning the prohibition of premature unofficial disclosure of the results of site visits, IRG review, and Council actions.

RELEASE OF SUMMARY STATEMENTS TO PRINCIPAL INVESTIGATORS

NIH takes very seriously its responsibility for informing principal investigators and their institutions about the outcome of grant application review. Over the years, NIH procedures and practices in this area have evolved from (1) routinely providing only the "bottom line" (i.e., "approval," "disapproval," or "deferral") to principal investigators and their institutions to (2) providing principal investigators, upon request, with important additional information, namely, paraphrased versions of the reviewers' critiques of their applications (the "reasons letters"). Because many of the comments and criticisms associated with a grant application pertain directly to the quality of the principal investigator's ideas, training, experiences, and accomplishments, NIH traditionally has viewed the reasons letter as a confidential communication to the investigator and has left to him/her the decision as to whether or not to share the letter with others.

In order to make the best use of the technical merit assessments of grant applications by peer reviewers, NIH staff is considering the feasibility and desirability of adopting additional or alternative approaches for communicating with principal investigators about the results of review. For example, some believe that the reasons letters should be sent out routinely on the initiative of NIH rather than strictly upon request. Others note that paraphrasing the contents of a summary statement produces, at best, only a good approximation of the reviewers' comments and, at worst, an account that is incomplete, inaccurate, or otherwise distorted as compared to the original. Still others point out that the task of preparing reasons letters is a significant component of the workload of BID extramural staff.

The Privacy Act has added a new dimension of concern. As now implemented, the BIDs provide edited summary statements, without priority scores, to principal investigators upon request, even if the request is received before a National Advisory Council/Board has completed action on the application. Therefore, under present NIH policies, an investigator who exercises his/her rights to the limit, may have an almost complete copy of the initial review group summary statement concerning his/her application even before a National Advisory Council/Board has had the opportunity to consider it. At the other extreme, an investigator who takes no initiative beyond submisson of an application may never learn anything more than the final action taken by a National Advisory Council/Board.

Given the importance that NIH attaches to good communications, it does not seem in the interests of either the principal investigators or the NIH to allow the information contained in summary statements to exist only in NIH files because investigators may not understand the law and/or NIH procedures well enough to know how to obtain these detailed critiques of their applications. Because of the foregoing concerns, the Study Team explored the question of whether NIH should go beyond its present practice of informing principal investigators about review results and, if so, what new approaches should be considered.

RECOMMENDATIONS AND DISCUSSION

1. THAT, AS SOON AS PRACTICAL AFTER A BID's NATIONAL ADVISORY COUNCIL/ BOARD COMPLETES THE REVIEW OF A GRANT APPLICATION, THE BID SHOULD ROUTINELY SEND THE SUMMARY STATEMENT, WITH THE PRIORITY SCORE DISPLAYED, TO THE PRINCIPAL INVESTIGATOR. BECAUSE SUMMARY STATEMENTS FREQUENTLY CONTAIN FORTHRIGHT AND CRITICAL COMMENTS CONCERNING THE PRINCIPAL INVESTIGATORS, THIS RECOMMENDATION IS MADE CONTINGENT UPON THE UNDERSTANDING THAT THESE DOCUMENTS WILL BE RELEASED BY NIH ONLY TO THESE INDIVIDUALS. IF IT IS DETERMINED THAT SUCH NIH-INITIATED RELEASE OF SUMMARY STATEMENTS COULD REASONABLY LEAD TO A REQUIREMENT THAT NIH MAKE THESE DOCUMENTS AVAILABLE ALSO TO APPLICANT INSTITUTIONS OR OTHERS, THEN THE STUDY TEAM RECOMMENDS THAT SUMMARY STATEMENTS WITH PRIORITY SCORES DISPLAYED BE RELEASED ONLY UNDER PRIVACY ACT PROCEDURES, I.E., UPON RECEIPT OF AN APPROPRIATE REQUEST FROM THE INDIVIDUAL CONCERNED.

   This recommendation was one of the most difficult for the Study Team to formulate and was arrived at only after agonizing deliberation. On the one hand, the Study Team is unanimous in believing that principal investigators deserve to have a detailed account of the results of review in a timely fashion and in a form that is most likely to be a complete and accurate account of the reviewers' findings and recommendations. On the other hand, the Study Team is unanimous in believing that NIH should take no action that would jeopardize or endanger the privacy rights of individuals. The Study Team would be deeply distressed if NIH-initiated release of summary statements to principal investigators somehow were to trigger or catalyze a chain of events (e.g., judicial actions or legislative reinterpretations) that caused the provisions of the Privacy Act no longer to apply to summary statements. Because of this ambivalence the Study Team elected to make its recommendation conditional and urges that NIH seek guidance on this matter at the earliest possible time.

   Carefully formulated as it is, the recommendation still engendered a significant diversity of reactions from Study Team members. Some regarded it as the strongest recommendation possible in the face of uncertainties about judicial and/or legal consequences and therefore endorsed it enthusiastically. Others feared that NIH-initiated mailing of summary statements, or reasons letters, to principal investigators would be interpreted by the scientific community as gratuitous communications or, even worse, as attempts to direct research. Consequently, they preferred the present practice of providing detailed accounts of review results only upon request. This latter group, within the Study Team, believed that the inefficiency associated with having principal investigators explicitly request summary statements or reasons letters is an acceptable price to pay for ensuring that detailed accounts of the results of review go only to those principal investigators who take specific action to obtain them.

Although routine release of summary statements to principal investigators would be an NIH initiative rather than the investigator's, the summary statements would nevertheless be processed consistent with current NIH Privacy Act procedures. This involves having them edited as necessary to ensure that the principal investigator receives only that information which pertains to him/her. While implementation of such a procedure clearly is feasible, it will produce some increase in the workload of BID officials thoughout NIH, especially during the weeks immediately following National Advisory Council/Board meetings.

The biomedical research community is becoming increasingly knowledgeable about the rights of individuals under the Privacy Act, and several BIDs are reporting an increase in the number of requests from principal investigators for the summary statements concerning their applications. Therefore, NIH-initiated release of summary statements is likely only to hasten a growth in workload that already is inevitable and shift it from officials designated to handle Privacy Act procedures to other BID officials.

The use of the summary statement as a vehicle for communication from NIH to principal investigators (whether at NIH's initiative or upon request) may present another problem. For those applications on which a National Advisory Council/Board acts in concurrence with the initial review groups' recommendations (the vast majority of cases), it generally will be sufficient to mail only the summary statements. However, for those applications on which a National Advisory Council/Board takes an action that is different from or in addition to that recommended by an initial review group, the BID would need to include, with the summary statement, an indication of the Council's/Board's decision and the supporting rationale. Case-by-case attention by senior BID staff therefore will be necesary. On the other hand, using summary statements to communicate with principal investigators would reduce the workload of BID extramural staff insofar as the preparation of reasons letters is concerned.

Despite these predictable difficulties associated with implementing its recommendation, the Study Team believes that the advantages of making summary statements readily available to principal investigators (hopefully at NIH's initiative) far outweigh the disadvantages. First, investigators would have more direct knowledge of the thoroughness and even-handedness with which peer reviewers carry out their tasks; this alone could do much to reduce concerns about the effectiveness and equity of this process. Second, principal investigators would have the benefit of valuable advice and consultation from a group of knowledgeable and distinguished experts. Third, the knowledge that summary statements are, ultimately, to be available outside NIH as well as within, would be an incentive for both those who prepare them and those who use them in decision-making to be certain that their contents are accurate, complete, and readable and that references to specific investigators are made with full respect for the dignity of the individuals involved. Fourth, if summary statements were to be released with the priority scores displayed, investigators would have a much clearer picture of how reviewers perceived the relative scientific merit of their applications and would be in a better position to appreciate how program relevance considerations and/or BID staff decisions affect their chances for an award. Fifth, NIH would be responsive to the advice of the scientific and lay public, for the concept of transmitting summary statements to principal investigators either automatically or upon request, received a relatively strong endorsement from both the participants in the NIH grants peer review system (Supplement 1) and some members of the public (both scientists and lay people) who testified at the public hearings.

Although the availability of summary statements, with priority scores displayed, to principal investigators, will provide them with potentially useful information about the scientific merit review of their applications, communications regarding the likelihood of awarding of approved applications are inadequate. It is not generally appreciated that, in addition to the scientific merit evaluation, subsequent decisions concerning award of approved applications are made at the BID level, based on programmatic and/or budgetary considerations. An accurate and clear explanation of these important additional considerations is essential to avoid misunderstandings and unjustified assumptions, on the part of unfunded investigators, regarding the quality of the scientific merit review of their applications; such misunderstandings frequently result in unjustified complaints about the peer review system.

2. THAT, WHEN, FOLLOWING COMPLETION OF THE INITIAL TECHNICAL MERIT REVIEW OF A GRANT APPLICATION BUT PRIOR TO FINAL ACTION BY A NATIONAL ADVISORY COUNCIL/BOARD, A BID COMPLIES WITH A PRINCIPAL INVESTIGATOR'S REQUEST FOR A COPY OF THE PERTINENT SUMMARY STATEMENT (AS PRESENT NIH POLICY FOR IMPLEMENTING THE PRIVACY ACT REQUIRES), THE BID SHOULD PROVIDE THE DOCUMENT WITH PRIORITY SCORE DISPLAYED AND ADVISE THE REQUESTOR THAT THE INFORMATION BEING TRANSMITTED IS INTERIM IN NATURE AND THAT ANY ATTEMPT, AT THIS POINT IN THE REVIEW PROCESS, TO MODIFY THE ORIGINAL APPLICATION OR PROVIDE COMMENTARY FOR CONSIDERATION BY THE COUNCIL/BOARD MAY RESULT IN A DEFERRAL OF THE APPLICATION TO THE NEXT REVIEW CYCLE.

The Study Team believes that, in complying with requests for summary statements under the Privacy Act before completion of the review process, BIDs should follow the same practice as is proposed in Recommendation 1 above, i.e., release the document with the priority score displayed. There seems to be no compelling reason why the priority score should be withheld in one case but made available in another. However, BIDs should make it clear to requestors that they are receiving interim information and that any attempt to influence the outcome of the review process, at this point, could produce significant delay.

3. THAT NIH SHOULD REQUEST AUTHORIZATION, THROUGH EITHER REGULATION OR LEGISLATION, AS APPROPRIATE, TO RELEASE AN INITIAL REVIEW GROUP SUMMARY STATEMENT TO THE PRINCIPAL INVESTIGATOR NAMED IN THE APPLICATION ONLY AFTER THE REVIEW OF HIS/HER GRANT APPLICATION IS COMPLETE, i.e. AFTER REVIEW BY NATIONAL ADVISORY COUNCIL/BOARD.

Under the present interpretation of the Privacy Act (as described above), principal investigators have the opportunity to obtain interim information about the review of their applications and to react to it, e.g., by submitting additional material and/or rebuttal statements. Ignoring the fact that such action most often will produce a delay in the review, the written interchange between a principal investigator and NIH could result in a more accurate assessment of the scientific merit of the application and the investigator's abilities. In fact, several participants in the public hearings stressed the desirability of incorporating a rebuttal step into the grants peer review procedure.

On balance, however, the Study Team believes that the release of interim information on the review of an application creates more problems than it solves. There will be occasions when an investigator challenges the review of an application the BID is prepared to fund anyway, and such reaction to premature information may serve no good purpose. There will be other occasions when an application, judged to be highly meritorious by an initial review group, is not selected for an award by the BID because a National Advisory Council/Board assigned a "low program relevance" rating; raising false hopes in an investigator with interim information only to dash them in a few months seems most unfortunate. The Study Team believes that the public interest would be better served if NIH were allowed to complete its peer review procedures before sending principal investigators an account of the reviewers' findings and recommendations. Moreover, if NIH's policies were changed such that summary statements were sent out automatically at the completion of the review process, the denial of requests for interim documentation would not affect what a requestor receives but only when he/she receives it and thus still would be consistent with the spirit of the Privacy Act.

PRIORITY SCORES ON SUMMARY STATEMENTS

Traditionally, NIH has assigned to each approved grant application, a numerical score signifying its relative scientific merit as perceived by an initial review group. This so-called priority score originally was determined by having each reviewer rate the application on a scale from 1.0 (the highest) to 5.0 (the lowest) in increments of 0.5, averaging the individual ratings, and multipying by 100. The resulting three-digit number came to be called the raw priority score and, for many years, was used uniformly throughout NIH.

But serious doubts about the process eventually developed. For example, a concern arose in several quarters of NIH that, consciously or otherwise, members of initial review groups sometimes might be assigning especially good priority scores to grant applications in certain areas of special interest to them, in the hope of increasing the likelihood that awards would be made. Similarly, some began to believe that reviewers sometimes express their lack of enthusiasm for certain areas of science by assigning comparatively low priority scores to all applications falling within those categories. Obviously, to the extent that review groups behave in these ways, the utility of the raw priority score as a true indicator of relative scientific merit *per se*, would be compromised.

In order to circumvent this, a mathematical procedure was devised to compare and adjust all the scores assigned at a given meeting of an initial review group in concordance with those ratings assigned at the group's two preceding meetings. The purpose of this procedure is to place the applications appraised by any one initial review group on a normal distribution curve. Thus, if an unusual number of applications were to be given scores higher or lower than the "normal" value (about 250), such scores would be redistributed on the curve so that most of them fall in the middle "normal" area where, in theory at least, they should fall. By this procedure, the mean score is adjusted to 250 and the standard deviation to 70. The resultant values are called the "normalized scores." The assumption underlying this statistical procedure is that, on the average, approved applications from the various NIH initial review groups are roughly equivalent in terms of scientific merit.

Currently, there appear on summary statements both the raw priority scores and the normalized ones (if the priority scores of 25 or more applications are available to be included in the normalization procedure). Each awarding unit has the option of using either system but is consistent in this regard. Confusion about the procedure can and does occur, however, particularly on the part of members of National Advisory Councils/Boards. Moreover, the normalization process can change the priority score significantly (on occasion, by 50 points), especially if reviewers consciously attempt to manipulate the procedure. When an adjustment of this magnitude is involved, it could easily mean the difference between award and non-award of a grant depending upon which score is used by the BID in making the awarding decisions. Because of its concerns about these matters, the Study

Team elected to review the present practices involving the raw and normalized priority scores and to attempt to determine whether any changes might be indicated.

RECOMMENDATIONS AND DISCUSSION

1. THAT A "SINGLE PRIORITY SCORE" CONVENTION SHOULD BE ADOPTED FOR USE THROUGHOUT NIH.

   The present practice of having both raw and normalized priority scores on summary statements and, leaving to each BID, the decision as to which convention it will follow, obviously, is viable and could be continued indefinitely, without irreparable harm to the grants peer review system. In the view of some NIH staff, however, it is becoming increasingly difficult to justify to themselves, to the scientific community, and to others interested in NIH's activities, why it is appropriate for something as fundamental as the convention for scoring the perceived scientific merit of a grant application to vary from one BID to another. Recognizing the significance which all BIDs attach to priority scores when they make award selections and other program management decisions, the Study Team believes that a single priority score convention for all of NIH would be preferable to the present practice.

2. THAT, BEFORE ADOPTING A SINGLE PRIORITY SCORE NOTATION SYSTEM FOR USE BY ALL BIDs, THE NIH SHOULD CONDUCT A STUDY OF BID PRACTICES REGARDING THE USE OF THE "RAW" AND "NORMALIZED" PRIORITY SCORES, TO DETERMINE WHETHER THE UNIFORM NIH-WIDE CONVENTION SHOULD BE THE USE OF THE RAW SCORE EXCLUSIVELY OR THE PRESENT NORMALIZED SCORES, WHENEVER THEY ARE AVAILABLE (OR OTHERWISE THE RAW SCORES), OR THE DEVELOPMENT OF A NEW PROCEDURE FOR COMPUTING, REPRESENTING, AND/OR ADJUSTING PRIORITY SCORES TO COMPENSATE FOR DIFFERENCES IN GROUP RATING BEHAVIOR.

   There is considerable difference of opinion among the NIH awarding units as to the relative utilities of the "raw" and "normalized" priority scores in their program management activities. Some BIDs use the raw scores exclusively in the belief that, at least for the initial review groups which serve their programs, the normalization procedure does more to confound the interpretation of scientific merit assessments than to reduce variance in the rating behavior of initial review groups, either between such groups or within the same group over time. Other BIDs take the opposite view. Because the issue is so important and the answer is not obvious, the decision to adopt a single priority score convention should not be taken until there has been a study of the relative strengths and weaknesses of the two alternative practices presently in use. Moreover, the Study Team recognizes that there also are other potentially useful methods for computing and/or mathematically adjusting scientific merit ratings and these also should be studied. For example, it has been suggested that the present three-digit representation for priority scores may imply a greater degree of precision in the initial review groups' ratings than they are able to achieve and that a more coarse representation (with or without mathematical adjustment to compensate for differences in group rating behavior) might be more appropriate.

3. THAT, UNTIL SUCH TIME AS A SINGLE NIH-WIDE PRIORITY SCORE NOTATION SYSTEM IS ADOPTED, ALL COPIES OF SUMMARY STATEMENTS WHICH A GIVEN BID SENDS TO PRINCIPAL INVESTIGATORS SHOULD DISPLAY EITHER THE RAW PRIORITY SCORE OR THE NORMALIZED PRIORITY SCORE (IF AVAILABLE) BUT NOT BOTH, DEPENDING UPON WHICH OF THE TWO CONVENTIONS THE PARTICULAR BID FOLLOWS.

   The display of dual priority scores on the copies of summary statements which are released to principal investigators would inevitably be a continuing source of difficulty for BID staff and others as they attempt to advise principal investigators about the outcome of the review process and their prospects for receiving an award. This difficulty can be avoided easily by instructing the staff of each BID to delete from the copies of summary statements which are to be sent to principal investigators the priority score that the BID does not use in its decision making. This special editing step would be needed of course, only until the NIH adopts a single priority score system and the printed summary statements then have only one score displayed.

4. THAT, NIH SHOULD CONDUCT STUDIES OF:

   a. VARIATIONS IN INDIVIDUAL REVIEWER AND REVIEW GROUP BEHAVIOR IN RATING APPLICATIONS, OVER TIME, AND AMONG DIFFERENT IRGs, AND OF THE FACTORS WHICH ACT TO INCREASE OR DECREASE SUCH VARIABILITY;

   b. VARIATIONS IN THE QUALITY OF GRANT APPLICATIONS ASSIGNED TO A GIVEN IRG FROM ONE REVIEW ROUND TO THE NEXT, OVER TIME; AND VARIATIONS IN THE QUALITY OF GRANT APPLICATIONS ASSIGNED TO DIFFERENT IRGs;

   c. THE EFFECTS ON THE REVIEW PROCESS OF DISPLAYING THE RAW PRIORITY SCORE TO THE INITIAL REVIEW GROUP MEMBERS IMMEDIATELY AFTER THEY ASSIGN THEIR INDIVIDUAL SCIENTIFIC MERIT RATINGS, AND OF GIVING THEM THE OPTION, AT THAT POINT, TO REOPEN DISCUSSON AND RERATE THE APPLICATION.

   The normalizing computation used by NIH is an indirect procedure for compensating for variability in IRG rating behavior over time. Studies a. and b. above would attempt to determine whether there are more direct approaches, such as the specific procedure suggested for trial in c., which might be used in conjunction with, or as a replacement for, the normalizing procedure to assure consistent, objective IRG ratings over time. Study b. would be a study to determine the extent to which differences among IRGs or within an

IRG overtime, in the average priority score and approval/disapproval ratio, reflect real differences in the quality of the applications under review rather than arbitrary shifts in group rating behavior. For study b., retrospective studies using citation methodology or the like, might be appropriate.

Under present initial review group procedures, each member ultimately expresses his/her view of the scientific merit of a grant application which is being recommended for approval by privately assigning a numeric rating. These individual ratings are collected by the executive secretary and his/her staff and averaged. Because the averaging of individual reviewers' ratings for any given application generally is not performed until well after the completion of the group's deliberations (often several days after the meeting), reviewers have no automatic feedback as to either what specific rating each member assigned or what the group's aggregate rating was.

There are several problems inherent in this procedure that, in the opinion of the Study Team, make a special study--and some experimentation with alternative approaches--seem warranted. First, because the group has only the primary and secondary reviewers' written comments and the subsequent oral exchange of opinions available at the time of rating, the members may not be fully aware of the nature or extent of differences of opinion which may exist within the group; and the Chairman may inadvertently terminate discussion when, in fact, further deliberation might be likely to produce a greater consensus. Second, without access to the resultant raw priority score, immediately following its discussion and rating of an application, the group has no opportunity to satisfy itself that the score is truly consistent with the spirit of its discussions and, if not, to reopen deliberations and possibly rerate the application. Under the present procedure it sometimes happens that the specific written and oral comments from which the executive secretary prepares the summary statement for an application are appreciably at variance (either more or less favorable in tone) with the implications of the priority score actually assigned.

There are a variety of techniques to effect quick feedback within initial review groups about individual reviewers' ratings and/or the aggregate score. These techniques range from the display of a hand-held score by each reviewer (as in done by judges of diving competitions) to the use of sophisticated electronic systems for instantaneous recording of individual ratings, computations of the aggregate score, and display of results. The Study Team recommends that NIH conduct a study comparing the present "no feedback" procedure with one or more alternatives involving immediate feedback about individual and/or group rating behavior. Such a study should include mechanisms to preserve the privacy of individual ratings by IRG members and should not be construed as a means to pressure IRG members to change their ratings. Rather, the study should be considered as a further means of studying rating behavior and an effort to develop an improved rating procedure.

GRANTS PEER REVIEW APPEALS SYSTEM

GRANTS PEER REVIEW APPEALS SYSTEM

In his April 28, 1975, memorandum establishing the NIH Grants Peer Review Study Team (GPRST), the Acting Director, NIH, asked the Study Team to address "the entire process of peer review," and to give specific attention to..."the need, advantages, and disadvantages for a technical merit review 'appeal' mechanism for applicants and an assessment of the process currently in use..." This suggestion led to formation of a Subcommittee on Appeals early in the activities of the GPRST. In addition to those members chosen from the Study Team, the Subcommittee was supplemented by additional members representing various functions in the grants peer review process in different BIDs. The substance of the report of the Subcommittee was adopted by the Grants Peer Review Study Team.

I. BACKGROUND

Several factors have led to concerns about an NIH grants peer review appeals process, most notably, perhaps, a portion of the Report of the House of Representatives Committee on Interstate and Foreign Commerce on the National Cancer Amendments of 1974. In that portion of the Report dealing with Peer Review of Grant Applications and Contract Projects, the Committee expressed the hope that NIH would take steps to ensure "...a just and proper recourse...to every unsuccessful applicant who wishes to appeal an adverse decision," and also voiced the feeling "...that, if the present appeals mechanisms are determined to be insufficient, it would be appropriate to consider the creation of an independent appeals process..." (1).

Other action in the 94th Congress focused more specifically on an appeals system for the National Science Foundation. Senate Bill S. 2427 and House Bill H. R. 9492 both suggested that NSF "...establish provisions for appellate procedures to independently review... proposals disapproved by the Foundation..." (Appendix I-1). While these two bills failed to be enacted, they presumably had some effect on the NSF directorate, which issued, in January 1976 an Important Notice on Reconsideration of Proposals Declined by NSF (Appendix I-2). This Notice aims to standardize the agency's methods for reconsideration of proposals which have been "declined," a term signifying that NSF will not provide grant support in response to an application.

Most specific to NIH and the Grants Peer Review Study Team tasks, a number of inputs to the GPRST have related to the need for an improved NIH grants review appeals system. Such opinions have been expressed in the three hearings held by the GPRST, have been received in a significant number of letters from the biomedical research community, and have appeared in comments on the questionnaire from members of NIH peer review committees. All of these comments focus on two broad aspects of an appeals system:

- The need to establish a system whereby an applicant may challenge the assignment of an application to an initial review group (IRG) for evaluation of scientific merit, and to a Bureau, Institute, or Division (BID) for funding considerations. Applicants have been concerned regarding difficulties with what they perceive as inappropriate assignments to IRGs which would allow an application to be evaluated by reviewers who may not be the best qualified to do so, or whose members might have potential biases in relation to the applicant institution, the principal investigator or staff, or the suggested project. Applicants sometimes also question the assignment to an awarding unit, or BID, which may have less potential interest in the proposed project than another BID.

- The need for a system which will enable an applicant-investigator to receive the total information which was utilized in making final recommendations on the application, and to have the opportunity to challenge or rebut such recommendations. Applicant-investigators sometimes perceive factual errors in review, e.g., data or information overlooked or not considered in the review, or data or statements misinterpreted by review groups. Or they may question the validity of judgments regarding the scientific evaluation, budget adjustments, or ethical or biohazard considerations of proposed projects.

A. Current Appeals Mechanisms (Appendix I-3)

The present NIH grants peer review system includes long-established and well-tested mechanisms for handling these processes regarding which suggestions have been made for improved handling of disputes or appeals. These involve the referral process, and the processes for communications regarding the outcome of scientific reviews, described elsewhere in this report.

1. Referral -- The receipt and assignment of applications involve several steps which are crucial and have important implications for the application as it moves through the peer review system. These functions are responsibilities of the Referral Branch in the Division of Research Grants (DRG), whose professional staff is selected on the basis of varied and specialized backgrounds suitable for determining the competencies of IRGs to review various applications, and for identifying appropriate granting components in light of their established areas of program interest. The primary consideration for IRG assignment is that the scientific methodology described in the application is best evaluated by eminently qualified scientists who, themselves, use or are familiar with the same methodologies. Assignment to a BID derives from an overall evaluation of the aims stated in the application and the investigator's statement of the significance of the proposed work. Actual assignments are based primarily on guidelines developed by DRG in collaboration with the BIDs.

2. Communications with Applicant-investigators

Summary statements relating the essential elements of a review group's considerations and recommendations are prepared by the executive secretary of that particular review group. Each summary statement follows a standard format in presenting a set of information points describing the application and explaining and justifying the review group's recommendations regarding the pertinent application and includes a priority score which expresses, in numerical terms, the group's assessment of the merits of the application. Summary statements from IRGs are presented to the National Advisory Councils for the final actions. In past years, investigators requesting the results of their reviews have been provided with abstracts of the summary statements, usually by the BID program staff responsible for the particular applications and projects involved. In more recent months, elements of the Privacy Act of 1974 have led to the release of summary statements to those investigators who request them.

B. Issues

Certain questions and problems have arisen in regard to both the referral process and communications about summary statements, which have led to detailed consideration by the GPRST:

1. Referral Process

a. How can applicant-investigators have an input into the referral process, in order to influence this process in a manner which would allow the appropriate decisions to be made by NIH, but which would take into consideration concerns of investigators that their applications be reviewed by groups most appropriate and competent to do so?

b. How can they express their concerns regarding certain groups or individual advisors responsible for such reviews, who, it is felt, are biased against the investigator or against the types of work or views suggested in the application?

c. How can investigators express their preferences that certain BIDs and corresponding National Advisory Councils consider their applications?

2. Communications

a. What information should be released regarding the outcome of review groups' deliberations? Should priority scores be included?

b. How should this information be communicated, i.e., by informal, oral communications, or by complete, written critiques?

c. To whom should the information be released, i.e., to a principal investigator only, or to institution officials, or co-investigators?

d. When should such information be released, i.e., immediately following an IRG meeting, or following a Council meeting?

e. How can investigators most expediently use whatever information is released, in formulating and appealing elements they feel have "gone wrong" in review of their applications?

3. General Issues

a. What elements of the review process should be made subject to appeal?

b. What recourse may be had to NIH offices outside those which are currently responsible for actions or decisions which rightly are subjects for appeal?

Approaches to some of these questions are covered in other portions of the GPRST Report. Aspects of these questions involving disputes, challenges, or other controversies regarding NIH peer review processes are considered in this section.

II. APPROACHES TO AN NIH GRANTS PEER REVIEW APPEALS SYSTEM

A. Current Elements of an Appeals System

It must be recognized that current NIH policies and procedures have been designed to handle certain aspects of the issues listed above. With regard to BID or IRG assignment, for instance, investigators may, and often do, suggest that applications be assigned to certain review groups or to certain BIDs. They may challenge the competence of the IRGs to which applications have been assigned, or may question the ability of specific members of assigned review groups to give recommendations without certain biases or prejudices against the applicant institution, the investigator, or the ideas suggested in the application. Such communications are usually received by and handled within DRG, which is responsible for the assignment procedures, and sometimes involve discussion between DRG and the BIDs.

Other procedures are available to and are practiced by investigators whose applications are not funded due to the grant peer review groups' recommendation either for disapproval or for approval at priority scores which do not permit funding. After receiving word of non-funding of an application and of the reasons leading to such a decision, the investigator may communicate further with the BID which is responsible for both the funding decision, and, at least, the initial communications to the applicant regarding that decision. In return, the investigator, but not the applicant-institution, may learn more detailed reasons for the recommendation regarding the application; such information is based on the summary statement, and may be excerpted from it; or the entire critique-text may be sent to the investigator. While such communications are conducted initially and primarily with the responsible BID, the investigator occasionally turns to the executive secretary of the IRG responsible for the scientific review, to learn more regarding the scientific rationale for the recommendation.

Furnished with these comments about the previous scientific reviews, the investigator is then free to submit a revised application, incorporating as many changes, as deemed desirable to meet the critical objections noted in regard to the original application. Over the past few years, such revised applications have constituted approximately ten percent of the review workload.

B. New Elements for a Formalized Grants Review Appeals System

While designed to handle most disputes arising in connection with the peer review of grant applications, the procedures now in force have certain deficiencies. Basic to most of these is the fact that the mechanisms for challenge or appeal are informal, handled on a person-to-person, *ad hoc* basis, without firmly established NIH policy. This, in turn, leads to a corollary difficulty in that the procedures are not widely known, even though NIH has taken some steps to provide accessibility of the revised application process to disappointed applicants. Moreover, the fact that different kinds of disputes are handled more or less entirely within the same NIH component, or even the same office, originally responsible for the assignement or review procedure, has led many investigators to feel frustrated in their attempts to seek relief from outside that component or office.

RECOMMENDATION 1:

THAT A FORMALIZED NIH GRANTS PEER REVIEW APPEALS SYSTEM BE ESTABLISHED TO CORRECT OR ELIMINATE THE DEFICIENCIES DESCRIBED ABOVE.

This system should have two phases to take into consideration those situations in which the assignment to a BID or an IRG may be challenged, and those in which elements of the scientific review may be challenged. In each case, the appeal must be made by the applicant-institution (or individual) formally applying for the grant, although the principal investigator may be responsible for informal communications regarding scientific aspects of the application. While the appeal or dispute must be received first by the office responsible for previous actions, the new appeals processes, in both cases, require that other officials and offices soon enter into the consideration and decision regarding the arguments proposed by the applicant and the investigator.

RECOMMENDATION 2:

THAT, IN ADDITION TO IMPROVEMENTS IN CURRENT PROCESSES FOR RECONSIDERATION OF ASSIGNMENTS OR REVIEWS, CERTAIN ENTIRELY NEW MECHANISMS BE ESTABLISHED FOR BOTH TYPES OF APPEAL TO HANDLE SITUATIONS WHICH DEMAND ACTION OR DECISION OUTSIDE THE ORIGINAL NIH COMPONENTS AND AT A HIGHER LEVEL.

RECOMMENDATION 2a:

...THAT, CENTRAL TO THESE NEW MECHANISMS BE THE ESTABLISHMENT OF THE POSITION OF OMBUDSMAN APPOINTED BY THE DIRECTOR, NIH.

Many of the responsibilities suggested below for receipt, processing, coordination, and documentation of decisions regarding appeals of disputed applications, should be assigned to the "Ombudsman." To be effective, such a person must be highly experienced with the grants peer review system but administratively independent of DRG and of the BIDs that actively operate the system.

While it is felt that it might be most expedient to handle appeals entirely within DRG, at least for certain types of appeals, it is recommended that resolution involving DRG and applicants should require a detached third party. The Ombudsman should be located in the Office of Extramural Research and Training (OERT), NIH, and should have the responsibility and authority to coordinate the processing of grant peer review appeals at higher levels.

RECOMMENDATION 2b:

...THAT, TO PROVIDE THE NEEDED HIGH LEVELS OF REVIEW RELATED TO APPEALS, THERE BE ESTABLISHED:

a. A GRANTS PEER REVIEW APPEALS BOARD (GPRAB), A PERMANENT COMMITTEE, THE MEMBERS OF WHICH WOULD ACT IN MATTERS CONCERNING ASSIGNMENT OF GRANT APPLICATIONS AND THOSE INVOLVING RECONSIDERATION OF SCIENTIFIC REVIEW OF APPLICATIONS (Table 1).

It should be chaired by the Ombudsman, should include two other permanent members from the Office of the Director (OD), and should include also three members of the Executive Committee for Extramural Affairs (ECEA) from separate BIDs, who would serve rotating terms which would expire in alternate years. An Executive Secretary should also be appointed.

b. GRANTS PEER REVIEW APPEALS PANELS (GPRAP), TEMPORARY GROUPS WHICH WOULD BE FORMED TO ACT IN THE FINAL STAGES OF DISPUTES CONCERNING THE SCIENTIFIC REVIEW OF GRANT APPLICATIONS (Table 1).

Each Panel should be selected by the Ombudsman, who should chair the group. Other members should include two from the GPRAB, of whom one would be from OD and the other from a BID, and two additional extramural staff from other BIDs. All BID members on a Panel should be from those BIDs not involved in the application dispute being considered. Additional scientific, administrative, and public members should serve on each Panel as required. An Executive Secretary should document the proceedings of each Panel.

III. CRITERIA FOR RECONSIDERATION OF NIH ACTION ON GRANT APPLICATIONS

RECOMMENDATION 3:

THAT THE FOLLOWING CRITERIA BE ESTABLISHED FOR RECONSIDERATION (APPEAL) OF NIH ACTION ON GRANT APPLICATIONS:

A. Who may initiate an appeal?

Only the applicant may initiate an appeal or request reconsideration of an application. The applicant is understood as the institution (or individual) formally applying for a grant award. The Principal Investigator (PI) will normally be the scientific representative of an applicant-institution and may be responsible for informal communications involving scientific aspects of that particular application, but to initiate a formal appeal, he/she must obtain the written endorsement of the applicant-institution.

B. What may be appealed?

An applicant may feel that it has reason to challenge or appeal either or both of the following situations during the peer review cycle:

1. Assignment of the application to an IRG or BID may be challenged and appealed after notification of the assignment. Prompt action by the applicant-institution should be encouraged in such cases, so that further consideration of the assignment may be accomplished in

the same review cycle. If an assignment is appealed after review, the applicant must explain and justify why the appeal was not entered earlier.

2. After receipt of the summarized comments pertaining to evaluation of the application, an applicant-institution may appeal the evaluation of the application if there is evidence that invalid judgements, inadequate review, or factual or administrative errors occurred in the scientific review. Such appeals may be made in any situation where the application does not result in a grant award; National Advisory Council or Board program or policy recommendations may not be challenged, however.

It is felt that, to a considerable degree, the proposed mechanisms, described below, for challenging or appealing assignments or reviews will accommodate situations covering appeals and disputes, before and after IRG review, and for all unfunded applications, whether favorably or unfavorably recommended. It is also recognized that instructions for applicants must make clear that any appeal may result in delays such that the application may be held until the succeeding Council round. Upon initiation of any appeal action, the pertinent application would be withdrawn from any further review or processing action pending resolution of that appeal. A similar delay would apply to any amended application, resubmitted while appeal of the original application is being considered. Further, appeal of any portion of a multi-project application e.g., program project or center grant, would require that the entire application be considered under appeal.

IV. MECHANISMS AND PROCEDURES FOR APPEALS CONCERNING ASSIGNMENT OF GRANT APPLICATIONS

RECOMMENDATION 4:

THAT MECHANISMS AND PROCEDURES BE ESTABLISHED FOR APPEALS CONCERNING ASSIGNMENT OF GRANT APPLICATIONS.

If not satisfied, upon notification of an assignment to an IRG or BID, the applicant-institution must proceed as outlined below (with number and letter references to the corresponding lines and columns in Figure 1):

An application (Line 1A) submitted to the DRG Referral Office (1B), is assigned to an appropriate IRG and BID (2B). The applicant-institution or its scientific representative, the PI, receives notification of and considers the assignment (3A) in light of his/her perceptions of the review process.

If dissatisfied, the applicant may request (4A) that the application be assigned to a different BID or IRG, or that specific reviewer(s) be excluded from the review, reasons for which must be detailed. Upon receipt of such a request (4B), the Referral Office decides (5B) on its validity. This appeal is communicated to the Associate Director for Scientific Review, DRG (6B), for his review and concurrence (7B). This is the first step at which the assignment is considered at a level above that where the decision was made originally. Upon receiving a communication about the DRG decision, the applicant considers the action (8A) and decides either to accept the decision (9A) or to submit a further appeal (10A).

If the applicant wishes to continue the appeal, it (including justification) is sent to the NIH Ombudsman (10C). The Ombudsman will form a group (11C) consisting of himself/herself plus two members of the Grants Peer Review Appeals Board (Table 2) who are from NIH components not involved in the appeal(12C). This group constitutes the next higher level of appeal regarding assignments. These three individuals will consult (13C) with the Executive Secretary of the involved IRG (14C), the staff of the BID involved (15C), and the Referral Office (16C) but then will reach an independent decision on the appropriate assignment (17C).

If this decision is to uphold the original assignment (18C), this is communicated to the applicant institution. There is no further recourse (22A). If, however, it is decided to change the assignment (19C) this decision is communicated to the applicant and to the Referral Office, DRG (20B) which will process the application as required by that decision (21B). The applicant will have no further recourse in regard to this revised assignment (22A).

V. PROPOSED MECHANISMS AND PROCEDURES FOR APPEALS CONCERNING SCIENTIFIC REVIEW OF GRANT APPLICATIONS

RECOMMENDATION 5:

THAT MECHANISMS AND PROCEDURES BE ESTABLISHED FOR APPEALS CONCERNING SCIENTIFIC REVIEW OF GRANT APPLICATIONS.

An appeal concerning the scientific review of a grant application will begin only after the PI receives the summarized comments of the review regarding the application as presented in the summary statement. Upon consideration of these comments the PI has three options: (1) to accept the summarized comments without further action; (2) to revise the application in response to the summarized comments and proceed as described below under A., "Resubmission for Review"; or (3) to invoke the appeals process as described below under B., "Appeal of the Scientific Review." As illustrated in Figure 2, appeal of the scientific review of a grant application starts with issuance by the BID of the summarized comments of the scientific review (1B). The PI considers these review comments (2A) and may decide, as one option, to take no further action (3A) or, as the other option, to revise and resubmit the application (4A).

A. Resubmission for Review

This form of appeal has always been available to the applicant and currently is used to a significant extent.

If the application is to be resubmitted, it should be revised in response to the summarized comments by the addition of new information or other amendments. Whatever modifications are made to the application must be indicated in a separate covering letter accompanying the resubmission. This will help reviewers in their reevaluation of the proposal and will also help prevent such material from being overlooked. Failure to point out these modifications could result in the application being returned without further review. Suggestions regarding IRG referral or use of specific reviewers may accompany the resubmitted application.

All this material and information is submitted to the Referral Office, DRG (4B) which will consider the documents and suggestions and assign the revised application to an appropriate IRG (5B). The latter will review the application during the next appropriate review cycle (6B), and its recommendations will be considered by the appropriate BID Council/Board (7B). If the applicant-institution, meanwhile, considers either of these two assignments inappropriate, a new assignment may be requested through the mechanism described above in Section IV.

B. Appeal of the Scientific Review

If the applicant-institution believes there were errors in the original review, an appeal of the evaluation may be made by requesting reconsideration of the review, with rebuttal of the comments (8A). Such a request should be sent to the BID which issued the results of the previous review (8B) and should give the reasons for the request for reconsideration, but submit no modifications to the application. The applicant should submit only such information as is appropriate to support this request for re-review, and must initiate the request within 90 days after the mailing date of the summarized comments, and, in any event, not later than 120 days after the Council/Board meeting.

The BID staff will consider the validity of this request for reconsideration (9B) and, in this process, will consult with the appropriate staff of DRG and the IRG responsible for the initial scientific review (10B). The BID may accept the validity of the request (12B) and may therefore return the materials to the IRG for rereview in the next cycle (13B) or to the BID Council/Board for its consideration (15B).

If however the BID staff considers the request for reconsideration invalid (11B), this decision will be communicated to the institution (12A), which may decide either to accept (14A) or appeal this decision (16A). Such an appeal should be directd to the NIH Ombudsman (16C), giving reasons for the request, *but again submitting no modifications to the application*, as mentioned above. The applicant should submit only such information as is appropriate to support this request for re-review, and must initiate this request within 20 working days after the mailing date of the BID communication denying the request for reconsideration (11B).

The Ombudsman will consult with two members of the GPRAB (17C), from NIH components uninvolved in the appeal (18C). This *ad hoc* group may decide to reject the request as one not falling within the jurisdiction of the peer review appeals system (19C), or to consider the request further through formation of a Grants Review Appeals Panel (20C) (see also Table 1). The Panel may decide (21C) to reject the institution's appeal (22C). Neither the *ad hoc* group's rejection (19C) nor the GPRAP's rejection (22C) may be appealed further by the applicant (21/22A). The Panel may decide, however, that the application deserves further consideration by an IRG (23B) or by an appropriate Council/Board (24B) and may so act. In doing so, the Panel should have authority to decide to what extent the application was adversely affected in the review and to direct the IRG or Council/Board to reconsider previous actions. The NIH appeal process ends with the decision of this Panel, which is reported to the applicant, the BID, and to DRG.

CONCLUSION

The Grants Peer Review Study Team believes that these recommended mechanisms involve both improvements on current procedures and suggestions for new ones. These principles for an Appeals System will furnish the basis for new and improved NIH policy and procedures to handle disputes and should, in turn, help greatly towards better understanding by and equity for members of the broad biomedical scientific community.

TABLE 1

GRANTS PEER REVIEW APPEAL GROUPS

Grants Peer Review Appeals Board - GPRAB

Appointed by Associate Director for Extramural Research and Training (ADERT), NIH

Members: 1 - OERT - Ombudsman - chair
2 - OD - permanent
3 - ECEA (BIDs) - rotate/alternate

Executive Secretary - appointed by ADERT

Grants Peer Review Appeals Panel - GPRAP

Selected by Ombudsman

Members: 1 - Ombudsman - chair
2 - GPRAB (1 OD + 1 BID, from uninvolved BIDs)
2 - NIH extramural staff (*ad hoc*)
+ Additional scientific/administative/public consultants, as required

Executive Secretary - selected by Ombudsman

FIGURE 1

ACTIONS TO RECONSIDER ASSIGNMENT OF GRANT APPLICATIONS TO IRG OR BID

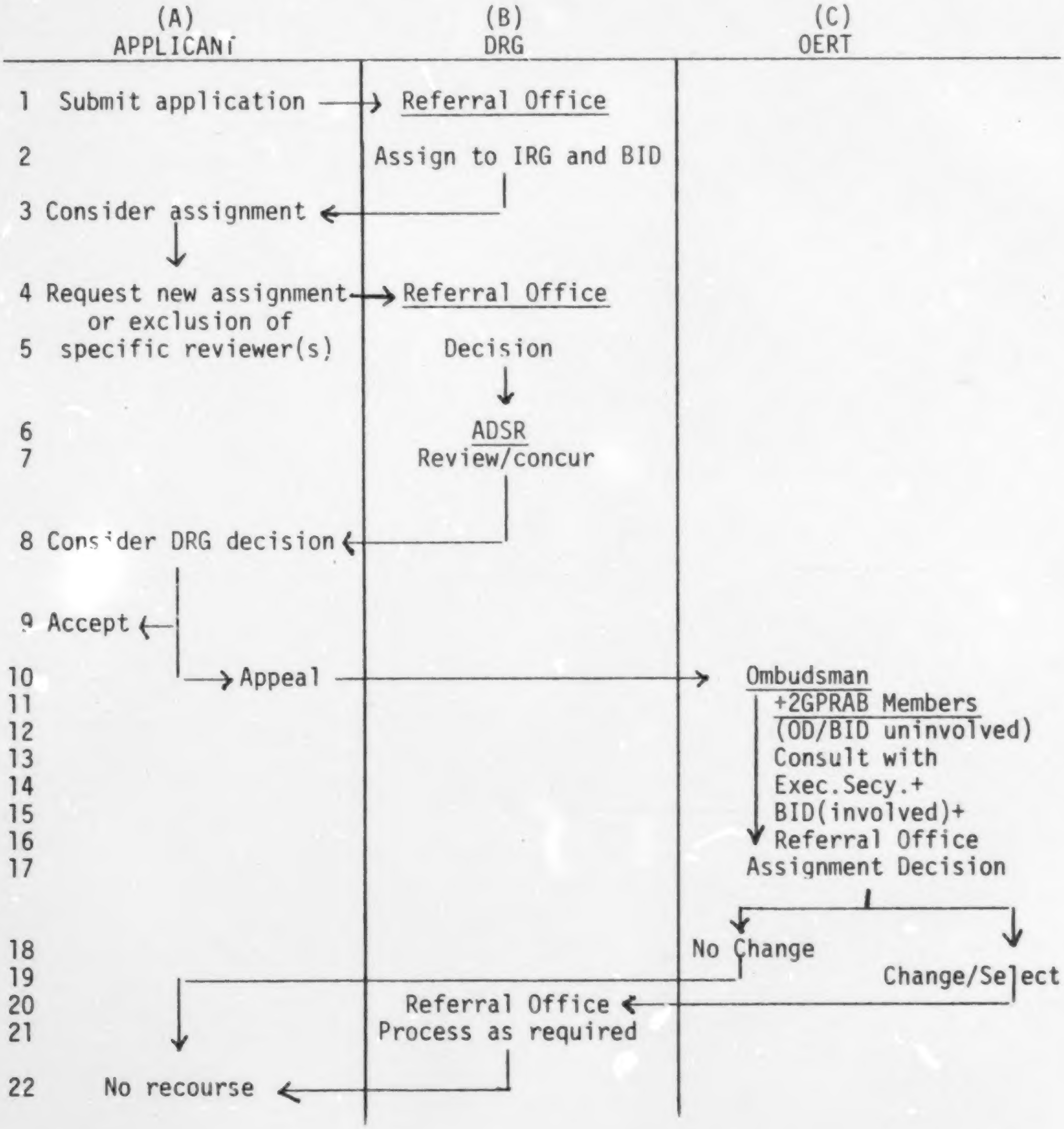
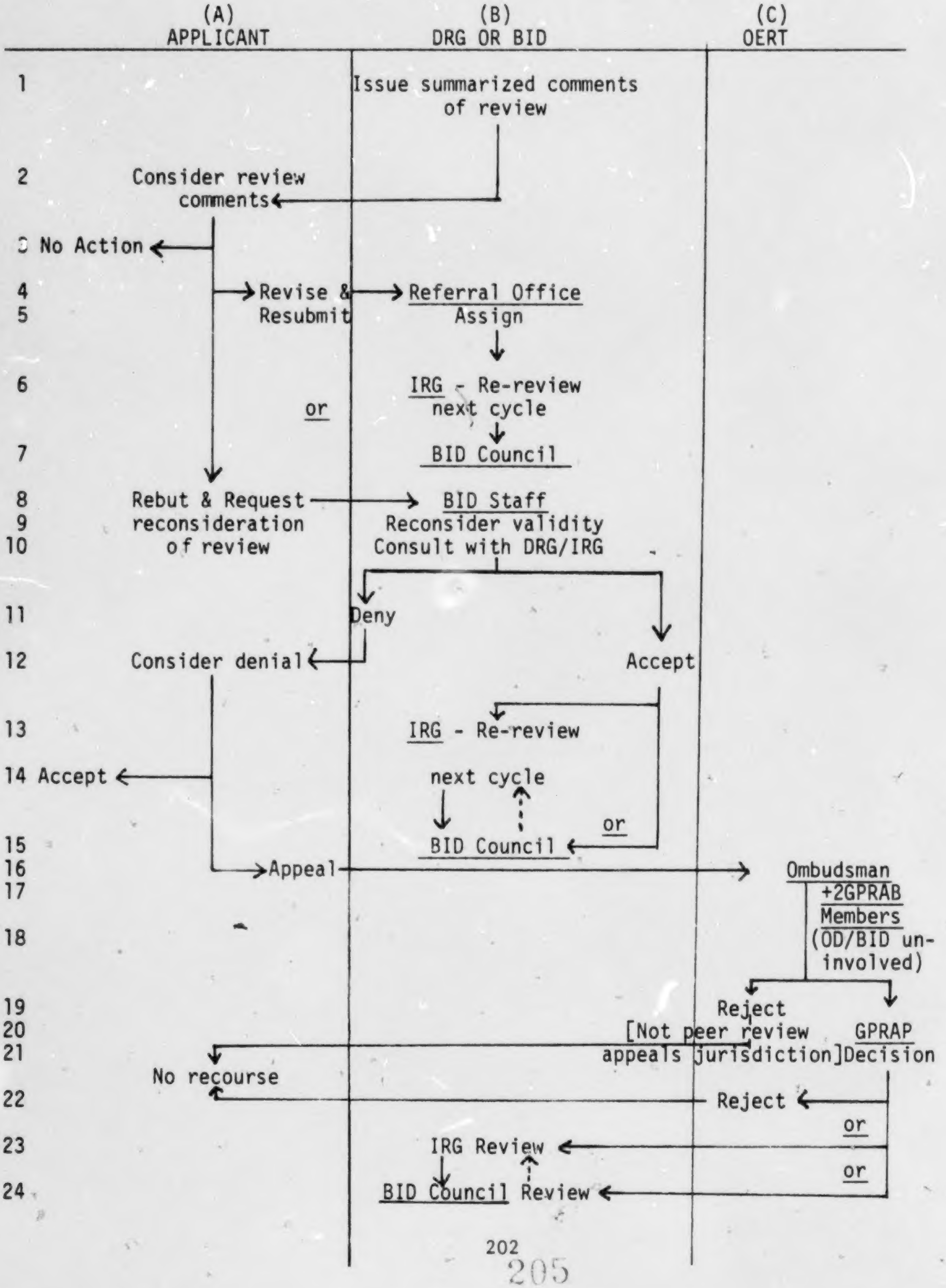

(A)
APPLICANT
(B)
DRG
(C)
OERT
1
Submit application
Referral Office
2
Assign to IRG and BID
3
Consider assignment
4
Request new assignment or exclusion of specific reviewer(s)
Referral Office
5
Decision
6
ADSR
7
Review/concur
8
Consider DRG decision
9
Accept
10
Appeal
Ombudsman
11
+2GPRAB Members
12
(OD/BID uninvolved)
13
Consult with
14
Exec.Secy.+
15
BID(involved)+
16
Referral Office
17
Assignment Decision
18
No Change
19
Change/Select
20
Referral Office
21
Process as required
22
No recourse

FIGURE 2

ACTIONS TO RECONSIDER OR APPEAL SCIENTIFIC REVIEW OF GRANT APPLICATIONS


(A)
APPLICANT
(B)
DRG OR BID
(C)
OERT
1
Issue summarized comments of review
2
Consider review comments
3 No Action
4
5
Revise & Resubmit
Referral Office
Assign
6
IRG - Re-review next cycle
or
7
BID Council
8
9
10
Rebut & Request reconsideration of review
BID Staff
Reconsider validity
Consult with DRG/IRG
11
Deny
12
Consider denial
Accept
13
IRG - Re-review
14 Accept
next cycle
or
15
BID Council
16
Appeal
Ombudsman
17
+2GPRAB Members
18
(OD/BID uninvolved)
19
Reject
20
[Not peer review appeals jurisdiction]
21
GPRAP Decision
No recourse
22
Reject
or
23
IRG Review
or
24
BID Council Review

ABBREVIATIONS USED

ABBREVIATIONS USED

AAMC - Association of American Medical Colleges

ADAMHA - Alcohol, Drug Abuse, and Mental Health Administration

ADERT - Associate Director for Extramural Research and Training

ADSR - Associate Director for Scientific Review

AIBS - American Institute of Biological Sciences

ARA - Awaiting receipt of application (a file)

ARC - Availability Request Clearance

ASH - Assistant Secretary for Health (in DHEW)

BHM - Bureau of Health Manpower

BID - Bureaus, Institutes, Divisions

BMC - Business Management Consultant

CCC - Comprehensive Cancer Centers

C.F.R. - Code of Federal Regulations

CMO - Committee Management Office(r)

CSRS - Cooperative State Research Service (USDA)

CV - *Curriculum vitae*

DBER - Division of Biomedical and Environmental Research (ERDA)

DCG - Division of Contracts and Grants

D.D.C. - District Court of the District of Columbia

DHEW - Department of Health, Education, and Welfare

DMP - Division of Management Policy

DRG - Division of Research Grants

DRR - Division of Research Resources

ECEA	- Executive Committee for Extramural Activities
ERDA	- Energy Research and Development Administration
ESRAC	- Executive Secretaries' Review Activities Committee
FACA	- Federal Advisory Committee Act
FOIA	- Freedom of Information Act
F.R.	- Federal Register
F. Supp.	- Federal Supplement
FY	- Fiscal Year
GMAC	- Grants Management Advisory Committee
GPRAB	- Grants Peer Review Appeals Board*
GPRAP	- Grants Peer Review Advisory Panel*
GPRST	- Grants Peer Review Study Team
HEW	- Department of Health, Education, and Welfare
HEW-474	- Confidential Statement of Employment and Financial Interests
HEW-532	- Request for Approval of Nominees for Public Advisory Committees
HEW NIH OD 0300	- Designation for the official NIH files concerning grants, fellowships, and certain other types of awards
H.R.000	- House of Representatives Bill
H. Rep.	- House Report
IMPAC	- Information for Management, Planning, Analysis, and Coordination; the computer-based record-keeping system of DRG
IRG	- Initial Review Group
MEDLAR	- Medical Literature Analysis and Retrieval System (of National Library of Medicine)
MEDLINE	- MEDLARS on-line service
MRC	- Medical Research Council

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*Projected

NAC/B - National Advisory Council/Board

NAS - National Academy of Sciences

NASA - National Aeronautics and Space Administration

NCI - National Cancer Institute

NEI - National Eye Institute

NHLBI - National Heart, Lung, and Blood Institute

NIA - National Institute on Aging

NIAID - National Institute of Allergy and Infectious Diseases

NIAMDD - National Institute of Arthritis, Metabolism, and Digestive Diseases

NICHD - National Institute of Child Health and Human Development

NIDR - National Institute of Dental Research

NIEHS - National Institute of Environmental Health Sciences

NIGMS - National Institute of General Medical Sciences

NIH - National Institutes of Health

NIMH - National Institute of Mental Health

NINCDS - National Institute of Neurological and Communicative Disorders and Stroke

NLM - National Library of Medicine

NSF - National Science Foundation

OCR - Office of Collaborative Research

OD - Office of the Director, NIH

OERT - Office of Extramural Research and Training

OGC - Office of General Counsel

OLS - Office of Life Sciences (NASA)

ONR - Office of Naval Research

OPPE - Office of Program Planning and Evaluation
PA - Privacy Act
PHS - Public Health Service
PI - Principal Investigator
P.L. - Public Law
PSAC - President's Science Advisory Committee
PSV - Project Site Visit
RB - Referral Branch
RFA - Request for Application
RFP - Request for Proposal
R 01 - Investigator-initiated research grant application
SAB - Statistics and Analysis Branch
SBMP - Subcommittee on Business Management Practices
SCOR - Specialized Centers of Research
S. 000 - Senate Bill
S. Rep. - Senate Report
SIRG - Special Initial Review Groups
SRB - Scientific Review Branch of the Division of Research Grants
SS - Study Section
SSS - Special Study Section
U.S.C. - United States Code
USDA - United States Department of Agriculture
VA - Veterans Administration

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